

EPA Registration No.  
75318-6  
Vol. 1

**Receipt for Section 3**

S:  Resubmission: ☐ Yes ☒ No

Regulatory Type:  Fee For Service: ☐ Yes ☒ No

Application Type:  Billable: ☐ Yes ☒ No

Company:  ☒ V

Risk Manager:

Product #:  Product Name:

Override#:

Me Too Section3:  Me Too Product Name:

Application Date:  ☒ OPP Rec'd Date:  ☒

Front End Date:  ☒ Risk Manager Send Date:  ☒

FFS Due Date:  Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Form A: ☐ Signature Date:  Form B: ☐ Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content:

Print Letter

Enter More Information

Tracking

Pria Resubto 345666

Mari D. 784882 | B67  
D345666 | 17

Pria Due 11/30

LA received 10/24/05

AIO  
OCT 14 2005

sdh  
2

**Registration Details**

Company: 75318 B2E BIOTECH LLC

Risk Mgr: RM 91 Biologicals & Pollution Prevention Division, PM Team 91

Organization: BPPD / BPB

Current Status: Under Review (18-Mar-2004)

Reg. Number: 75318-A Pesticide Type: Biochemical High Exposure? ☐

Use Type: EP Signal Word: Caution

Repack: ☐ Yes ☒ No

NPIC Phone: ☐ Yes ☒ No WPS Written Notification: ☐ Yes ☒ No

**Related Products**

Use Patterns Transfer History Toxicology Mode Of Action FR Notice Receipts

**Product Name** Ingredient Formulation Property Pesticide Category Permitted State

Product Name	Name Status
B2E-01	Active

JUN 03 2005 BPPD

WPS-PPE

Label Image

Container Info

Tracking

Status

Sites/Pests

CSF

Data Requirements

Generate Rqmts

Inert Ingredients

EPA-OPP Main - C...

4:59 PM

779777 | 350  
 MD | 38

Mari  
 350  
 Request to Renegotiate  
 4/4  
 LH

AIO  
 JUN 6 2005  
 sdh



**Receipt for Section 3**

S: 773047

Regulatory Type: Product Registration - Section 3 ☒ Resubmission: ☐ Yes ☒ No

Application Type: Pending Product Amendment ☒ Fee For Service: ☐ Yes ☒ No

Company: 75318 B2E BIOTECH LLC ☒

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 81

Product #: 75318-A Product Name: B2E-01

Me Too Section3: Me Too Product Name:

Application Date: 14-Jan-2005 ☒ OPP Rec'd Date: 14-Jan-2005 ☒

Front End Date: 18-Jan-2005 ☒ Risk Manager Send Date: 18-Jan-2005 ☒

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Form A: ☒ Signature Date: Form B: ☐ Signature Date:

New Ingredient Request Date: New Ingredient Received Date: Signature Date:

Receipt Content: Study

773047 / B67  
ND / 13

AIO  
FEB 4 2005

sdh 4



**Receipt for Section 3**

S: 773333

Regulatory Type: Product Registration - Section 3 ReSubmission: ☐ Yes ☒ No

Application Type: Pending Product Amendment Fee For Service: ☐ Yes ☒ No

Company: 75318 B2E BIOTECH LLC. V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 75318-A Product Name: B2E-01

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 24-Jan-2005 ☒ OPP Rec'd Date: 25-Jan-2005 ☒

Front End Date: 26-Jan-2005 ☒ Risk Manager Send Date: 26-Jan-2005 ☒

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Form A ☐ Signature Date: Form B ☐ Signature Date:

Receipt Content: Study

JAN 28 2005 *BPAD*

773333 / B67  
ND / 37

L7 reply in Agency ltr  
28Mar05 for S773047

B67

Resub

Mari

DID not find. to screen  
not needed

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FEB 4 2005

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# Receipt for Section 3

S: 769791

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Application Type: New Registration

Fee For Service: ☐ Yes ☒ No


Company: 75318 B2E BIOTECH LLC V


Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 75318-A Product Name: B2E-01


Override#:

Me Too Section3: Me Too Product Name:

Application Date: 26-Oct-2004 

OPP Rec'd Date: 27-Oct-2004 

Front End Date: 

Risk Manager Send Date: 28-Oct-2004 

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Revised label in support of pending application.

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Receipt Content

Rec'd.  
OCT 28 2004  
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NOV 15 2004  
sdh 6



**DATA PACKAGE BEAN SHEET**

Date: 02-Sep-2004

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**\*\*\* Registration Information \*\*\***

Registration: 75318-A - B2E-01

Company: 75318 - B2E BIOTECH LLC

Risk Manager: RM 91 - Sheryl Reilly - (703) 308-8269 Room# CM-2 910D

Risk Manager Reviewer: Mari Duggard MDUGGARD

Sent Date: 18-Mar-2004

Calculated Due Date: 05-Oct-2004

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (B67) NEW PRODUCT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;

Ingredients: 105402, Isopropyl (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate(33.6%)

**\*\*\* Data Package Information \*\*\***Expedite: ☒ Yes ☐ No

Date Sent: 31-Aug-2004

Due Back: \_\_\_\_\_

DP Ingredient: 105402, Isopropyl (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate

DP Title: \_\_\_\_\_

CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #: \_\_\_\_\_

**Assigned To****Date In****Date Out**

Organization: BPPD / BPB

Administrative Due Date: 01-Mar-2005

Team Name: \_\_\_\_\_

Negotiated Due Date: \_\_\_\_\_

Reviewer Name: \_\_\_\_\_

Projected Completion Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

**\*\*\* Studies Sent for Review \*\*\***

Printed on Page 2

**\*\*\* Additional Data Package for this Decision \*\*\***

No Additional Data Packages

**\*\*\* Data Package Instructions \*\*\***

Note to Contractor/ EPA Reviewer: This product, B2E-01 is an insect growth regulator, containing 33.6% (S)-Methoprene for which the company B2E Biotech LLC is seeking registration. The studies associated with this data package are (1) Product Chemistry and (2) Product Performance. Please review all data in its entirety and provide reviews for MRID #s 46225401-5 and 46225407. Please also review Volume 3B, for which we have no MRID as of September 02, 2004. The study was rejected for improper formatting of one page and does not affect the overall conclusions/review of the study.



DP#: (307472)

\*\* Studies Sent for Review \*\*

Decision#: (345666)

MRID	Citation Reference	Guideline
46225401	Mintz, W. (2004) Product Identity and Composition, B2E 01. Project Number: B09/03/0012A. Unpublished study prepared by B2E Biotech LLC. 9 p.	830.1550/Product Identity and cor
46225402	Mintz, W. (2004) Description of Materials Used to Produce the Product, B2E 01. Project Number: B03/04/0012B. Unpublished study prepared by B2E Biotech LLC. 51 p.	830.1600/Description of materials
46225403	Sjoogren, R. (2004) Description of the Formulation Process, B2E 01. Project Number: B03/04/0012C. Unpublished study prepared by B2E Biotech LLC. 11 p.	830.1620/Description of productio
46225404	Minz, W. (2004) Certified Limits, B2E 01. Project Number: B02/04/0012D. Unpublished study prepared by B2E Biotech LLC. 9 p.	830.1750/Certified limits
46225405	Sjogren, R. (2003) B2E 01 Product Performance Summary and Bridging Data. Project Number: B09/03/0013A. Unpublished study prepared by B2E Biotech LLC. 112 p.	810.3400/Mosquito, black fly, and
46225407	Floore, T.; Petersen, J.; Shaffer, K.; et. al. (2003) Assessment of B2E 01 Insect Growth Regulator EC (33.6% AI) Formulation Against Ochlerotatus taeniorhynchus in Small Plot Field Studies. Project Number: DTG09/03/0013C. Unpublished study prepared by B2E Biotech LLC. 8 p.	810.3400/Mosquito, black fly, and



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Biopesticides and Pollution Prevention Division (7511C)  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

EPA Reg. Number:

75318-6

Date of Issuance:

DEC 27 2005

## NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

B2E-01

Name and Address of Registrant (Include ZIP Code):

B2E Biotech, LLC  
500 Mamaroneck Ave., Suite 201  
Harrison, NY 10528

784882 / B67  
D345666 / 17

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c)(5) provided you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA Sec.3 (c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA Sec. 4.
2. Revise the EPA Registration Number to read, "EPA Reg. No. 75318-6."
3. Submit two (2) copies of your final printed label for the record, before you release the product for shipment.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Date:

CONCURRENCES

EPA Form SYMBOL	7511C	7511C						
SURNAME	Duggard	Ruby						
DATE	16 Dec 05	12/27/05						



**B2E-01**  
**An Insect Growth Regulator**

**MASTER LABEL, includes:**

**Sublabel A:** Control of insect pests in tobacco processing and storage facilities  
**Sublabel B:** Prevent the emergence of adult Sciarid flies in mushroom culture  
**Sublabel C:** Prevent the emergence of stored product insects  
**Sublabel D:** Prevent the emergence of adult filter flies & non-biting midges  
**Sublabel E:** Prevent the emergence of adult floodwater mosquitoes

**ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #65733-16-6)..... 33.6%

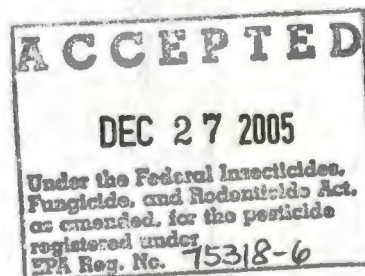
**OTHER INGREDIENTS:**..... 66.4%

**TOTAL:**..... 100.0%

EPA Reg No. (Pending as File Symbol 75318-A)

EPA Est. No. XXXXX-XX-XXX

B2E Biotech LLC  
500 Mamaroneck Avenue  
Harrison, NY 10528



NET CONTENTS: \_\_\_\_\_

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See (back panel) (side panel) (insert label) for additional precautionary statements

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**FIRST AID**

<b>If in eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If on skin</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If swallowed</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor for treatment advice</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give any liquid to the person.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-XXX-XXX-XXXX for emergency medical treatment information.

**ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of equipment washwaters or rinsate.

B2E-01; EPA Reg. No. (Pending as File Symbol 75318-A)

Label version (28) dated December 27, 2005

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<b>Sublabel A: Control of insect pests in tobacco processing and storage facilities</b>
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**FOR PROTECTION OF STORED TOBACCO FROM DAMAGE BY  
CIGARETTE BEETLE (*LASIODERMA SERRICORNE*) AND  
TOBACCO MOTH (*EPHESTIA ELUTELLA*)**

**INTRODUCTION**

**B2E-01** is an emulsifiable concentrate formulation of the insect growth regulator, (S)-Methoprene. It is designed for use as a space spray in cold aerosol generators and in liquid concentrate form as an aqueous emulsified spray. Unlike traditional pesticides, (S)-Methoprene does not immediately kill immature insects; instead, it interferes with the normal insect development process and prevents adult pest emergence. **B2E-01**, prevents the adult emergence and reproduction of the Cigarette beetle (*Lasioderma serricorne*) and Tobacco moth (*Ephestia elutella*) when used according to label directions.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

**APPLICATION WITH COLD AEROSOL GENERATORS**

Apply **B2E-01** as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply **B2E-01** at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment that will achieve uniform dispersal for best treatment results.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for a minimum of 30 minutes (longer if possible) to allow the fine spray mist to settle. Do not remain in treated areas after treating. Ventilate treated areas before reentry. Repeat application as required.

**APPLICATION AS AN AQUEOUS SPRAY**

Prepare a diluted spray solution by adding 1 ml of **B2E-01** to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Repeat application as required.

**MIXING INSTRUCTIONS**

Partially fill clean application tank with water, add the specified amount of **B2E-01**, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## **Sublabel B: Prevent the emergence of adult Sciarid flies in mushroom culture**

### **AN INSECT GROWTH REGULATOR TO PREVENT THE EMERGENCE OF ADULT SCIARID FLIES IN MUSHROOM CULTURE**

**(WPS Language to be included in the Precautionary Statements)**

#### **Personal Protection Equipment (PPE)**

Some materials that are chemical-resistant to this product are listed below. For more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, such as neoprene rubber ( $\geq 14$  mils), nitrile rubber ( $\geq 14$  mils), barrier laminate, or viton ( $\geq 14$  mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **Engineering Control Statements:**

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)]. The handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

#### **User Safety Recommendations:**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### **INTRODUCTION**

S-Methoprene, the active ingredient in **B2E-01** insect growth regulator (IGR), is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of S-Methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. **B2E-01** prevents the emergence of adult Sciarid flies from the mushroom growing medium. When used as directed, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adult flies present at the time of application will not be affected. If high adult fly populations are present, an initial use of a conventional adulticide will insure the best overall results. After treatment with **B2E-01**, larvae will continue to develop to the pupal stage where they will die. As **B2E-01** prevents adult fly emergence, adult fly populations will be reduced over time. As maximum control is achieved two weeks after treatment, control assessment should be made at this time for most accurate evaluation.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

#### **AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification to workers, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses on this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

**B2E-01**; EPA Reg. No. (Pending as File Symbol 75318-A)

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Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber ( $\geq 14$  mils), nitrile rubber, ( $\geq 14$  mils), barrier laminated, or viton ( $\geq 14$  mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.

## METHOD, RATE, AND TIMING OF APPLICATION

Use either METHOD A, METHOD B, METHOD C or METHOD D.

### A. INCORPORATE AT TIME OF CASING

Apply **B2E-01** at the rate of  $5\frac{1}{2}$  fluid ounces (fl oz) per 1,000 square feet (sq ft). Apply evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface immediately after placement.

### B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING WHEN CASING LAYER IS PLACED ON COMPOST

#### IN COMPOST

Apply **B2E-01** at the rate of  $5\frac{1}{2}$  fl oz per 1,000 sq ft in adequate water for even distribution. Spray on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

#### IN CASING

Apply **B2E-01** at the rate of  $2\frac{1}{2}$  fl oz per 1,000 sq ft. Apply evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

### C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a spawn run longer than 15 days, a split application can be used.

#### FIRST APPLICATION, ON COMPOST

Apply **B2E-01** 12 to 13 days after spawning. Drench **B2E-01** evenly on the surface at the rate of  $2\frac{1}{4}$  fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### SECOND APPLICATION, IN CASING

Apply **B2E-01** at the rate of  $2\frac{1}{4}$  fl. oz. per 1,000 sq ft. Apply evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

### D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS

#### FIRST APPLICATION, IN CASING

Apply **B2E-01** at the rate of  $5\frac{1}{2}$  fl. oz. per 1,000 sq. ft. in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### SECOND APPLICATION, ON CASING SURFACE JUST PRIOR TO FIRST BREAK

Apply **B2E-01** at the rate of  $2\frac{1}{4}$  fl. oz. of per 1,000 sq. ft. in adequate water for even distribution as a surface drench prior to first break of mushrooms.

## MIXING AND HANDLING INSTRUCTIONS

Partially fill clean application tank with water, add the specified amount of **B2E-01**, mix, and complete filling with water. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

**B2E-01**; EPA Reg. No. (Pending as File Symbol 75318-A)  
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## **EFFECT ON MUSHROOMS**

In most cases, treatment with **B2E-01** has a beneficial effect on mushroom yield by reducing Sciarid fly larval damage. As mushroom production practices differ among growers, the user can conduct small plots treatments to verify that reduced crop yields will not occur under cultural conditions used.



## Sublabel C: Prevent the emergence of stored product insects

### AN INSECT GROWTH REGULATOR TO CONTROL STORED PRODUCT INSECTS IN STORED FOOD COMMODITIES, SUCH AS CEREAL GRAINS, GRAIN SORGHUM (MILO), CORN, POPCORN, BIRDSEED, PEANUTS, SUNFLOWER SEEDS & TO CONTROL INSECT PESTS IN SEEDS

#### INTRODUCTION

(S)-Methoprene, the active ingredient in **B2E-01**, protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, **B2E-01** is not an adulticide, but its residual activity prevents the development of larvae from developing into adults. **B2E-01**, when used according to the label directions, prevents regeneration of these and other insect pests: Almond Moth (*Ephesia cautella*), Indian Meal Moth (*Plodia interpunctella*), Cigarette Beetle (*Lasioderma serricorne*), Lesser Grain Beetle (*Rhyzopertha dominica*), Sawtooth Grain Beetle (*Oryzaephilus surinamensis*), Merchant Grain Beetle (*Oryzaephilus mercator*), Red Flour Beetle (*Tribolium castaneum*), and Confused Flour Beetle (*Tribolium confusum*). Treat existing insect populations with an adulticide before applying **B2E-01** for residual protection.

Apply **B2E-01** to any food commodity (including but not limited to: cereal grains, corn, sunflower, canola, popcorn, wheat, spices, sorghum, rice, cocoa, peanuts, oats, and millit) for control of insect larvae. Use **B2E-01** to treat pet food, animal feedstuffs, birdseed, and cotton hulls. **B2E-01** can be applied to seed stock. Treated commodities can be processed within 24 hours following application.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

**Stored Commodities:** For protection of stored food, grains, animal feed, seeds used for oil and seed stock against stored product insects – for optimum results, thoroughly clean and treat storage areas prior to storing commodities. Apply **B2E-01** to a top-dressing to stored products that have already been placed into bins or storage areas. For top-dressing applications, spray or fog the bin headspace paying particular attention to the top on the commodity mass, beams, ceilings, and rafters. Thorough coverage is essential. For surface treatments, apply 1 ml (1/30 oz.) of **B2E-01** per 1000 square feet; or for space spray, apply 3 ml (1/10 oz.) per 10,000 cubic feet in sufficient water to provide adequate coverage. Do not flood top-dress area.

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED:** Dilute **B2E-01** with water and apply to the moving grain stream as a uniform coarse spray. Final water dilution volume is 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. Lower volumes of diluent can be used but, it is important to assure that the commodity mass is uniformly treated. Agitate water dilution during application.

A range of rates for different commodities is provided for flexibility during varying storage periods and conditions. For maximum residual, use higher rates; the lowest application rate offers shorter residual for commodities stored  $\leq 6$  months.

Apply **B2E-01** in solution in accordance with the general directions, to stored products at the following rates per 1,000 bushels:

	<u>fl oz</u>	<u>ml</u>	<u>fl oz</u>	<u>ml</u>	<u>fl oz</u>	<u>ml</u>
Wheat	14.0	420	7.0	210	1.75	52
Corn	14.0	420	7.0	210	1.75	52
Sorghum (Milo)	14.0	420	7.0	210	1.75	52
Barley	12.0	360	6.0	180	1.50	45
Rice	12.0	360	6.0	180	1.50	45
Oats	8.0	240	4.0	120	1.0	30
Peanuts	8.0	240	4.0	120	1.0	30
Sunflowers	8.0	240	4.0	120	1.0	30

**B2E-01**; EPA Reg. No. (Pending as File Symbol 75318-A)

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For information on rates for other commodities, contact your distributor.

### USE NOTES:

- Apply **B2E-01** grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Partially fill clean application tank with water, add the specified amount of **B2E-01**, mix, and complete filling with specified quantity of water.
- Use diluted spray solution within 72 hours of mixing. Agitate before each use.
- Clean up extremely dusty sites prior to application.

Use **B2E-01** as a fogging concentrate or surface spray for the treatment of stored product pests and other insect pests infesting warehouses, silos, storage bins, or other stored commodity areas. Apply **B2E-01** in food processing, food service, food preparation, and food handling establishments including mills, bakeries, restaurants, taverns, industrial buildings, breweries, candy processing, pet food production, grocery stores, modes of transportation (rail cars, ships, and trucks), cereal processing and bottling facilities. Apply **B2E-01** to packaged, canned, and bottled foodstuffs, as well as boxes, liners, and pallets. For application of **B2E-01** as a fogging space spray, use the following directions.

### APPLICATION WITH COLD AEROSOL GENERATORS

Apply **B2E-01** as a mist or aerosol. Dilute with water following the instructions of the spray equipment manufacturer. Apply **B2E-01** at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment. Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

### APPLICATION WITH AEROSOL GENERATORS

Apply **B2E-01** as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply **B2E-01** at the rate of 1 ml (1/30 oz) per 1000 square feet of surface area or 3 ml (1/10 oz.) per 10,000 cubic feet. Use appropriate spray equipment to achieve uniform coverage.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave room closed for 30 minutes to allow spray mist to settle. Do not remain in the treated areas and ventilate before re-entry. Repeat application as required.

### APPLICATION AS AN AQUEOUS SPRAY

To prepare a diluted spray solution, partially fill the mixing container with water, add 1 ml (1/30 oz) of **B2E-01**, mix and complete filling with a total of 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with a low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

When tank mixing **B2E-01** with conventional aqueous adulticides, the more stringent label will apply.

## **Sublabel D: Prevent the emergence of adult filter flies & non-biting midges**

### **PREVENTS THE EMERGENCE OF ADULT FILTER FLIES AND MIDGES - KEEPS INFESTATIONS UNDER CONTROL**

#### **INTRODUCTION**

**B2E-01** is a unique emulsifiable concentrate formulation that controls filter flies (*Psychodidae*) and non-biting midges (*Chironomidae*) in waste water treatment facilities. **B2E-01** contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. **B2E-01** does not control adults but prevents the larval stage from developing into flying adults. **B2E-01** keeps pest infestations under control by stopping the reproduction cycle, without shutting down your treatment facility. Regular use of **B2E-01** prevents these pests from developing into annoying infestations.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **APPLICATION DIRECTIONS**

##### **WASTE WATER TREATMENT FACILITY PESTS**

Use **B2E-01** in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges and filter flies are a problem.

##### **WHAT TO EXPECT IN CONTINUOUS FLOW WASTE WATER TREATMENT FACILITIES**

To achieve effective results, **B2E-01** must be applied to continuous flow systems on a daily basis for 10 days. A gradual reduction in the number of adult pests will be seen over a 7 day period with significant reduction seen after 14 days of treatment. Failure to apply **B2E-01** daily may produce erratic results. Very heavy infestations often require slightly longer to achieve the desired control level. Since the mode of action of **B2E-01** is to prevent adult emergence, pupa and adults present at the time of initial application will complete their life cycle. Pest populations can be expected to rebound within 2-3 weeks following the last day of treatment.

##### **SLUDGE OR SOLID WASTE APPLICATIONS**

For sludge solid waste applications, use 3 ounces per million gallons of sludge or solids. Apply dilution until the drying beds have been filled, then stop the application. Make applications at the influent side as the sludge or solids enter into the drying beds. Application of **B2E-01** to solids will prevent pest insect emergence and keep infestations under control.

#### **APPLICATION METHODS**

##### **WASTE WATER TREATMENT FACILITIES**

Dilute **B2E-01** with water prior to use. Apply **B2E-01** by use of a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence product dilution. Prepare the desired volume of dilution to apply over a 6-8 hour period, or in cases of sludge drying beds, apply until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of **B2E-01** over a 6-8 hour period.

#### **APPLICATION RATES**

##### **WASTE WATER TREATMENT PESTS**

To control waste water pests, apply 3 ounces of **B2E-01** per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply at the influent side over a 6-8 hour period during the lowest flow period of the day. For best results, make the application on a daily basis for 10 days or until suppression of pests is achieved.

##### **APPLICATION TO WASTE WATER - TRICKLING FILTER**

Apply 3 ounces of **B2E-01** per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply the material. Apply at times of low flow periods (typically evening through early morning hours) for 6-8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 10 days or until suppression of pests is achieved.



## **MIXING AND HANDLING INSTRUCTIONS:**

Partially fill clean application tank with water, add the specified amount of **B2E-01**, mix, and complete filling with water. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## **APPLICATION SITES**

### **WASTE WATER TREATMENT FACILITIES**

Make applications of **B2E-01** to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem. Make **B2E-01** applications as the sewage enters (influent areas) the waste water treatment area. For best results, apply to the influent side.

## Sublabel E: Prevent the emergence of adult floodwater mosquitoes

### PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES

#### INTRODUCTION

**B2E-01** provides effective levels of S-Methoprene insect growth regulator to prevent the emergence of adult floodwater mosquitoes from treated water. **B2E-01** can be applied either diluted in water or used to make granules. Treated larvae continue to develop normally to the pupal stage where they die. **B2E-01** prevents the emergence of adult floodwater mosquitoes (*Aedes*, *Ochlerotatus* and *Psorophora*) from treated water.

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For use by mosquito abatement districts.

#### APPLICATION DIRECTIONS

Apply **B2E-01** to 4th instar floodwater mosquito larvae prior to pupation to prevent adult emergence. Apply **B2E-01** in the late afternoon or evening to extend the effective control window. Proper treatment timing is important for best results. Using conventional liquid application equipment, apply the amount of **B2E-01** listed below in sufficient water to give complete coverage. Do not apply when weather conditions will cause drift from the areas to be treated. Do not reapply product for 7 days. Use **B2E-01** granules to make treatments under windy conditions or to dense vegetation.

**NOTE:** The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

#### APPLICATION RATES

Apply 0.5 ounce to 1.0 ounces (15 to 30 ml) of **B2E-01** per acre in water. Application of **B2E-01** to sites subject to water flow or exchange will diminish the product's effectiveness.

#### MIXING AND HANDLING INSTRUCTIONS

Partially fill clean application tank with water, add the specified amount of **B2E-01**, mix, and complete filling with water. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

#### APPLICATION SITES

Apply **B2E-01** as directed above to floodwater habitats which support mosquito larval development. Examples of typical sites are: freshwater and salt water marshes, woodland pools and meadows, grassy swales, floodplains, irrigated croplands, pastures and rangeland (without removal of livestock), vineyards, rice fields (including wild rice), fruit and nut orchards, berry fields and bogs, and other natural and manmade depressions where mosquitoes may breed. In dense vegetation or canopy areas, use **B2E-01** to make granules on sand or other carrier following preparation instructions detailed below. Apply **B2E-01** Granules using standard granular dispersal equipment.

#### B2E-01 GRANULES:

Granules can be made using washed, dry sand or other carriers. Apply **B2E-01** to the granule quantity to be applied per acre. For example, to apply 1.0 fl. oz./acre dosage rate on 5 pounds of granules per acre: Add 98 pounds of washed dry sand into a small rotary cement mixer. Tilt mixer to an angle 20° above horizontal. Measure out 20 fl. oz. of **B2E-01**, and add to a sprayer equipped with a flat fan nozzle. Pressurize sprayer and turn on mixer. Spray **B2E-01** on the rolling face of the sand until it is evenly dampened. Mix for 2 minutes, then add a drying agent (Microcel E or Hisil 233) as needed, to achieve a dry, free flowing granule. Discharge granules and bag. Apply within 72 hours.

Dosage Rate Oz./Acre	Granule Application Rate/Acre (Lbs.)	Ounces of B2E-01 to 99# of washed sand
0.5	2.5	20
0.5	5.0	10
0.5	10.0	5
0.75	2.5	30
0.75	5.0	15

**B2E-01; EPA Reg. No. (Pending as File Symbol 75318-A)**  
Label version (28) dated December 27, 2005

Page 10 of 11



0.75	10.0	7.5
1.0	2.5	40
1.0	5.0	20
1.0	10.0	10

## **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal.

### **PESTICIDE STORAGE**

Store in a cool, dry place.

### **PESTICIDE DISPOSAL**

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

### **CONTAINER DISPOSAL**

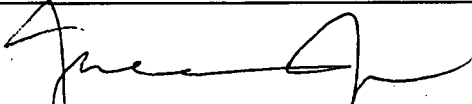
Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. Do not reuse container.

## **WARRANTY AND CONDITIONS OF SALE**

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. To the fullest extent permitted by law, buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Always read the label before using this product.

For information, call 1-XXX-XXX-XXXX or visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 345666		Registration#: 75318-A
Fee Category: B67		PRIA Decision Time Frame:
Submitted by: Mari Duggard	Branch: BPB/BPPD	Date: 11/23/05
Company: B2E		
Original Due Date: 12/29/04	Proposed New Due Date: 12/30/05	
Previous Negotiated Due Dates: 6/28/05; 10/31/05; 11/30/05		
<p><b>Issue (describe in detail):</b>  Questions remain to be resolved between EPA and the company about how this product will be used for mosquito control in floodwaters. The product is only effective for 1 day, but the company intends there to be a limited time for this formulation. Methoprene (the active ingredient) is very sensitive to UV light and there is no UV protection in this formulation. The company is preparing information and has sent some information to BPPD electronically today. We need time to resolve this and company is willing to give us 30 days. Hopefully this is the last renegotiation.</p>		
<p><b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b>  Email and telephone conversations. The company would rather give an extension than get a registration without the mosquito use included. They have provided data (although not of high quality) to address issues we have raised in the reviews to date.</p>		
<p><b>Rationale for Proposed Due Date:</b>  30 days should be enough time to resolve remaining issues.</p>		
Other Comments:		
Approved: <input checked="" type="checkbox"/>	Disapproved:	
If disapproved, action to be taken:		
OD or DOD Signature: 		





Amy Roberts  
<ARoberts@tsgusa.com>  
11/22/2005 04:50 PM

To Janet Andersen/DC/USEPA/US@EPA  
cc Bill Mintz <bmintz@b2ecorp.com>  
bcc  
Subject B2E-01 (75318-A) - Renegotiation

History:  This message has been replied to.

Dear Janet:

Further to my voicemail message, we would prefer to renegotiate out the PRIA due date for this pending product rather than receive an label approval without mosquitoes. Bill Mintz (B2E) has indicated that B2E-01 is for a very specific use during the mosquito's life cycle. Bill is going to draft up an explanation as well as think about some more targeted label language to explain how, when and why the product is to be applied. We will plan on having that information to the Agency on Monday, November 28, via email correspondence.

As our interactions on this label will not involve the submission of new data, I would like to suggest that the push out the PRIA due date for 30 days, to December 30, 2005.

I will be out of the office Wednesday - Friday of this week, so will plan on communicating more with you next Monday on this matter. Have a great Thanksgiving holiday. Regards,

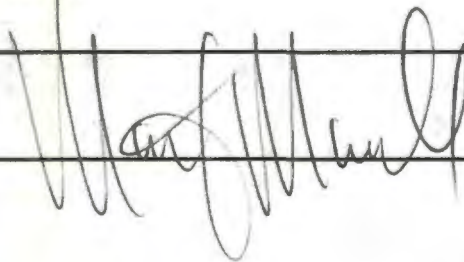
Amy Plato Roberts  
Technology Sciences Group Inc.  
1101 17th Street, NW, Suite 500  
Washington, DC 20036  
Direct dial: (202) 828-8964; Fax: (202) 872-0745  
www.tsgusa.com

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 345666		Registration#: 75318-A
Fee Category: B67		PRIA Decision Time Frame: 6 months
Submitted by: Mari Duggard	Branch: BPB	Date: 21 Oct 2005
Company: B2E Biotech, LLC		
Original Due Date: 29 Dec 2004	Proposed New Due Date: 30 November 2005	
Previous Negotiated Due Dates: 28 Mar 05; 28 June 05; 31 Oct 05		
<p><b>Issue (describe in detail):</b>  This registration application is for an Insect Growth Regulator containing 33.6% S-Methoprene, to be formulated into pellets for use in tobacco processing and storage facilities. Four data requirements of the toxicity six pack have not been adequately satisfied through the submitted waiver requests, non-target organism data to support the aquatic use sites on the label have not been adequately addressed, and the product performance data was classified as Upgradeable. With the last renegotiation (31 Oct 05), BPPD placed a caveat on the agreement stating that the resubmission must have been received by 15 Jul 05. This "received-by" date was missed and a teleconference with the registrant and his consultant was held to discuss the situation, upon which they assured BPPD the resubmission would soon be delivered. The resubmission to the 28 Mar 05 Agency deficiency letter was received on 3 Oct 05 and is currently being reviewed. The package includes Acute toxicity data waiver requests, as well as environmental effects public literature information and label changes to reflect the efficacy of the product, according the product performance data.</p>		
<p><b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b>  The registrant was notified of major deficiencies in the application package through 15 Dec 04 and 28 Mar 05 deficiency letter, e-messaging communications throughout the review process, and off-agenda conversations with the registrant at a Pre-registration meeting. Each time BPPD has renegotiated the decision date for this pending product (and others) submitted by B2E Biotech, LLC it has been with the understanding that the required studies were currently being generated or were almost ready to submit. Yet, to date the registrant is still submitting public literature, in lieu of testing to satisfy the non-target organism data requirements and toxicity waiver requests.</p>		
<p><b>Rationale for Proposed Due Date:</b>  Since the resubmission is currently being reviewed by the Agency, one months time will allow for the review and correction of any deficiencies that may be identified within the resubmission.</p>		



**Other Comments:**

The registrant has been reminded that removal of the unapproved aquatic use sites may help to get this product registered (since it also lists other non-aquatic use sites) and that he can submit an amendment request later when the required data has been generated.

**Approved:** ✓**Disapproved:****If disapproved, action to be taken:****OD or DOD Signature:**

10-27-05



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 75318-A	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) B2E-01	PM# 91/Biochemical Pesticides Br./BPPC	
5. Name and Address of Applicant (Include ZIP Code) B2E Biotech LLC 500 Mamaroneck Avenue, Suite 201 Harrison, NY 10528 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>3/28/05</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Resubmission in response to an Agency deficiency letter dated March 28, 2005. Refer to the attached cover letter (dated September 28, 2005) for details.

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> on container label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Amy Plato Roberts; aroberts@tsgusa.com		Title Regulatory Consultant		Telephone No. (Include Area Code) (202) 828-8964	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped) 
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Amy Plato Roberts		5. Date September 28, 2005			



**WASHINGTON**

1101 17th Street, N.W.

Suite 500

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Sheryl Reilly  
Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511C)  
Office of Pesticide Programs, EPA  
1801 South Bell Street  
Arlington, VA 22202

September 28, 2005

**RE: B2E-01; File Symbol 75318-A****Resubmission in response EPA letter dated March 28, 2005****SACRAMENTO**

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Dear Dr. Reilly:

Enclosed with this letter you will find the following in response to the Agency's deficiency letter dated March 28, 2005:

- 1) Resubmission 8570-1 form;
- 2) Copy of the March 28, 2005 deficiency letter;
- 3) Revised Confidential Statement of Formula;
- 4) Updated Data Matrix Table; including a publicly-releasable "blacked-out" version;
- 5) One (1) copy of a revised label with all changes highlighted in redline;
- 6) Five (5) clean copies of the revised label;
- 7) Supplemental data waiver rationale volume for specific acute toxicity data requirements.

**CANADA**

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

A point-by-point response to the Agency's deficiency letter is as follows:

**Confidential Statement of Formula**

A revised Confidential Statement of Formula is attached that makes the correction noted by the Agency.

**Toxicology**

Supplemental data waiver rationales for Acute Inhalation Toxicity, Primary Eye Irritation, Primary Skin Irritation and Dermal Sensitization have been submitted. New rationales include additional quantitative data and/or literature for each specific route of exposure, as well as additional discussion on the potential for human exposure from each route.

**Product Performance Data**

The product label directions for use sections have been revised to address the comments raised in the product performance data review. Specific directions, rates and method of application have been removed until such a time as new





Page 2 of 3  
September 28, 2005  
B2E-01

**WASHINGTON**

1101 17th Street, N.W.

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**SACRAMENTO**

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Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

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data can be generated and submitted to the Agency for review and approval.

**Non-Target Organism Data**

B2E-01 is an emulsifiable concentrate formulation, which contains 33.6% active ingredient, and is applied as a dilute spray to target use sites. As this formulation is not encapsulated, it is subject to rapid degradation by sunlight upon application in aquatic environments. The half life of methoprene in the environment is reported to be less than 4 hours (Schaefer et al. 1997) and less than 1 day (Quistad et al. 1975). As such, this end-use product is anticipated to achieve no more than 1 day of control. In addition, it should be noted that data on file for the active ingredient shows the technical grade product is not acutely toxic to fish or aquatic invertebrate species during short-term exposures.

Previously, the Agency has expressed concerns about potential chronic or repeat application hazards to non-target organisms in estuarine and marine environments from methoprene applications. Because this formulation has a short duration (1 day), and due to the proposed label restriction that limits reapplication for 7 days, there is a reasonable certainty of no harm to estuarine and marine non-target organisms from use of the product. As such, we believe the estuarine and marine use sites on the proposed label are supported by the data on file.

*A copy of references cited is included with this cover letter.*

**Data Matrix**

An updated data matrix, that includes recent submissions, is attached.

**Product Label**

The product label has been revised to include all changes required by the Agency, with the exception of the following:

- a. Net contents are not listed as package sizes may vary. Anticipated net contents are found in Section III of the original application form (EPA Form 8570-1).
- b. Revised application methods and rates have been provided for the directions for use to prevent emergence of adult sciarid flies in mushroom culture (page 4). Revised methods and rates are based on the registrant's recent experience with mushroom growers.
- c. Label restrictions on application to estuarine and marine use sites have not been included. Instead, a reapplication restriction has been included ("Do not reapply product for 7 days."; Page 10). As this product has short





Page 3 of 3  
September 28, 2005  
B2E-01

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**WASHINGTON**

1101 17th Street, N.W.

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Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

term exposure, we believe there is no concern for potential chronic or repeat application hazards to non-target aquatic organisms. Refer to the comments in the Non-target Organism Data section of this letter for the rationale.

Per recent correspondence, this application has a PRIA Due Date of November 30, 2005. If you have any questions or comments, please do not hesitate to contact Bill Mintz (B2E Biotech; (631) 537-9797) or myself.

Sincerely,

Amy Plato Roberts  
Regulatory Consultant for B2E Biotech LLC  
Direct dial (202) 828-8964; email: [aroberts@tsgusa.com](mailto:aroberts@tsgusa.com)

**SACRAMENTO**

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

cc: Bill Mintz, President, B2E Biotech LLC

**CANADA**

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

VOLUME 1 OF 2 OF SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

B2E Biotech LLC  
500 Mamaroneck Avenue  
Harrison, NY 10528

REGULATORY ACTION:

Resubmission of supplemental data to support a pending registration for **B2E-01 (75318-A)**

TRANSMITTAL DATE:

September 28, 2005

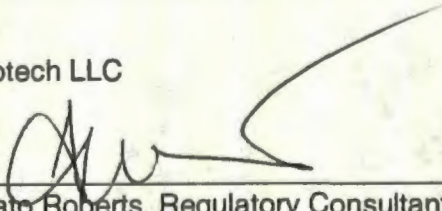
LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	OPPTS GUIDELINE NUMBER
	1 of 2	(Transmittal Document)	-----
46656001	2 of 2	Supplemental Response to Tier 1 Biochemical Pesticide Data Requirements for B2E-01	870.1300, 870.2400 870.2500, 870.2600

COMPANY NAME:

B2E Biotech LLC

COMPANY OFFICIAL:

  
Amy Plato Roberts, Regulatory Consultant for B2E Biotech LLC

COMPANY CONTACT:

Amy Plato Roberts  
Technology Sciences Group Inc.  
1101 17<sup>th</sup> Street, N.W., Suite 500  
Washington, D.C. 20036  
Direct dial (202) 828-8964; Email: [aroberts@tsgusa.com](mailto:aroberts@tsgusa.com)

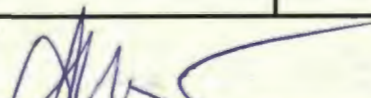


**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W. WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The Public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPP Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date <b>September 28, 2005</b>			EPA Reg. No./File Symbol <b>75318-A</b>		Page <b>1</b> of <b>4</b>
Applicant's/Registrant Name and Address  <b>B2E Biotech LLC</b> <b>500 Mamaroneck Avenue, Suite 201</b> <b>Harrison, NY 10528</b>			Product  <b>B2E-01</b>		
Ingredient <b>(S)-Methoprene (CAS No. 65733-16-8)</b>					
<b>Guideline Reference Number</b>	<b>Guideline Study Name</b>	<b>MRID Number</b>	<b>Submitter</b>	<b>Status</b>	<b>Note</b>
OPPTS 880.1100	Product Identity and Composition	462254-01	B2E Biotech LLC	OWN	
OPPTS 880.1200	Description of the Starting Materials Description of the Formulation Process (sp only)	462254-02 462254-03	B2E Biotech LLC B2E Biotech LLC	OWN OWN	
OPPTS 880.1400	Discussion of the Formation of Impurities	462254-03	B2E Biotech LLC	OWN	
OPPTS 830.1700	Analysis of Samples				Not required per 40 CFR 158.170.
OPPTS 830.1750	Certified Limits	462254-04	B2E Biotech LLC	OWN	
OPPTS 830.1800	Enforcement Analytical Method	457374-05	Hartz-B2E LLC	PER	
OPPTS 830.6302	Color		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.6303	Physical State		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.6304	Odor		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.6313	Stability at Normal and Elevated Temperatures, Metals and Metal Ions		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.6314	Oxidation/Reduction		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
Signature 			Name and Title <b>Amy Roberts, Regulatory Agent</b>		Date <b>September 28, 2005</b>



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**401 M Street, S.W. WASHINGTON, D.C. 20460**

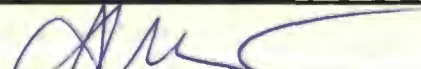
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**DATA MATRIX**

<b>Date</b> September 28, 2005	<b>EPA Reg. No./File Symbol</b> 75318-A	<b>Page</b> 2 of 4
<b>Applicant's/Registrant Name and Address</b>  B2E Biotech LLC 500 Mamaroneck Avenue, Suite 201 Harrison, NY 10528		<b>Product</b>  B2E-01

Ingredient (S)-Methoprene (CAS No. 65733-16-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6315	Flammability		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.6316	Explodability		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.6317	Storage Stability		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.6319	Miscibility		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.6320	Corrosion Characteristics		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.6321	Dielectric breakdown voltage		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.7000	PH		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.7050	UV/visible absorption		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.7100	Viscosity		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.7200	Melting Point		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.7220	Boiling Point		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.7300	Bulk Density		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.7370	Dissociation Constant		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.

<b>Signature</b> 	<b>Name and Title</b> Amy Roberts, Regulatory Agent	<b>Date</b> September 28, 2005
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**DATA MATRIX**

Date <b>September 28, 2005</b>			EPA Reg. No./File Symbol <b>75318-A</b>	Page <b>3 of 4</b>	
Applicant's/Registrant Name and Address  <b>B2E Biotech LLC 500 Mamaroneck Avenue, Suite 201 Harrison, NY 10528</b>			Product  <b>B2E-01</b>		
Ingredient <b>(S)-Methoprene (CAS No. 65733-16-8)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.7550	Partition Coefficient		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.7840	Water Solubility		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 830.7950	Vapor Pressure		B2E Biotech LLC	OWN	Self-Certification in ADMIN docs.
OPPTS 870.1100	Acute Oral Toxicity - Rat	464458-01	B2E Biotech LLC	OWN	
OPPTS 870.1200	Acute Dermal Toxicity - Rabbit	464458-01	B2E Biotech LLC	OWN	
OPPTS 870.1300	Acute Inhalation Toxicity - Rat	464458-01	B2E Biotech LLC	OWN	
OPPTS 870.2400	Primary Eye Irritation - Rabbit	464458-01	B2E Biotech LLC	OWN	
OPPTS 870.2500	Primary Dermal Irritation - Rabbit	464458-01	B2E Biotech LLC	OWN	
OPPTS 870.2600	Dermal Sensitization - Guinea Pig	464458-01	B2E Biotech LLC	OWN	
OPPTS 870.3100	90-Day Oral Toxicity - Rat			FOR	Formulator's Exemption
OPPTS 870.3250	90-Day Dermal Toxicity			FOR	Formulator's Exemption
OPPTS 870.3465	90-Day Inhalation Toxicity			FOR	Formulator's Exemption
Signature 			Name and Title <b>Amy Roberts, Regulatory Agent</b>		Date <b>September 28, 2005</b>

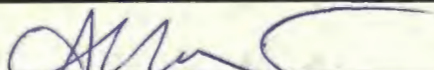


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Date <b>September 28, 2005</b>			EPA Reg. No./File Symbol <b>75318-A</b>		Page <b>4 of 4</b>
Applicant's/Registrant Name and Address  <b>B2E Biotech LLC 500 Mamaroneck Avenue, Suite 201 Harrison, NY 10528</b>			Product  <b>B2E-01</b>		
Ingredient <b>(S)-Methoprene (CAS No. 65733-16-8)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 870.3700	Tetratogenicity			FOR	Formulator's Exemption
OPPTS 870.5000	Genotoxicity			FOR	Formulator's Exemption
OPPTS 880.3550	Immunotoxicity			FOR	Formulator's Exemption
OPPTS 850.2100	Avian Acute Oral Toxicity	455434-01	Hartz-B2E LLC	PER	
OPPTS 850.2200	Avian Dietary Toxicity	455434-02	Hartz-B2E LLC	PER	
OPPTS 850.1075	Fish Acute Toxicity – Freshwater and Marine	455434-03	Hartz-B2E LLC	PER	
OPPTS 850.1010	Aquatic Invertebrate Acute Toxicity	455434-04	Hartz-B2E LLC	PER	
OPPTS 850.4100	Nontarget Plant Studies			FOR	Formulator's Exemption
OPPTS 880.4350	Nontarget Insect Studies			FOR	Formulator's Exemption
OPPTS 810 Series	Product Performance	426254-05 462254-07 463503-01 464530-01 464530-02	B2E Biotech LLC B2E Biotech LLC B2E Biotech LLC B2E Biotech LLC B2E Biotech LLC	OWN OWN OWN OWN OWN	
Signature 			Name and Title <b>Amy Roberts, Regulatory Agent</b>		Date <b>September 28, 2005</b>



# Environmental Degradation of the Insect Growth Regulator Methoprene (Isopropyl (2E,4E)-11-Methoxy-3,7,11-trimethyl-2,4-dodecadienoate). III. Photodecomposition

Gary B. Quistad,\* Luana E. Staiger, and David A. Schooley

5933 8

Photodecomposition products were characterized after irradiation of methoprene as a thin film on glass or silica gel, as an aqueous emulsion, and as a methanolic solution with added photosensitizer. The most abundant photoproduct of methoprene after illumination of a thin film or aqueous emul-

sion was 7-methoxycitronellal (9-14%). Methoprene was quite stable in methanolic solution although a slow reaction with singlet oxygen occurred. Isomerization of the 2-ene double bond to a mixture of cis-trans isomers was facile.

The utility of insect growth regulators (IGR's) as insect control agents is dependent partially on their photochemical stability. Photoinitiated decomposition probably contributes more to the environmental instability of IGR's than any other degradative mechanism. Methoprene (1, Altosid IGR, isopropyl (2E,4E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate) is a potent representative of a group of IGR's with juvenile hormone activity (Henrick *et al.*, 1973). Methoprene is effective in controlling dipterous larvae (Schaefer and Wilder, 1973; Harris *et al.*, 1973), but it is rapidly degraded under natural field conditions (Schaefer and Dupras, 1973).

This report represents part of a comprehensive study of the environmental fate of methoprene (for part II, see Schooley *et al.*, 1975). We report the products and reactions resulting from perhaps the most important mechanism of environmental lability—photodecomposition.

## EXPERIMENTAL SECTION

The methoprene used in these studies had the following purity: (2E,4E)-[5-<sup>14</sup>C]methoprene [97.9% 2E, 1.5% 2Z, 5.0 mCi/mmol]. The [5-<sup>14</sup>C]methoprene (Quistad *et al.*, 1974) was diluted to various specific activities with nonradioactive methoprene [98.5% chemical purity; 99.4:0.6, 2E:2Z ratio;  $\lambda_{max}$  259 nm ( $\epsilon$  28,000), hexane]. Radioactivity was quantified as discussed previously (Quistad *et al.*, 1974). Mass spectra were determined at 20 eV by coupled gas-liquid chromatography (glc)-mass spectroscopy (ms) (Quistad *et al.*, 1974). Nuclear magnetic resonance (nmr) spectra were determined on a Varian T-60 instrument. Infrared (ir) spectra were measured on a Beckman AccuLab 4. Ultraviolet (uv) spectra were determined on a Hitachi-Perkin-Elmer double beam spectrophotometer (Coleman 124).

**Aqueous Solution Photodecomposition. Rate of Reaction.** In order to assess the rate of aqueous photolysis, two 6-l. erlenmeyer flasks were filled with 4 l. of autoclaved phosphate buffer (0.05 M, pH 7). The sterilized water was aerated for 10 min by bubbling air from a stainless steel fritted filter (2  $\mu$ ) through the solution. One flask was dosed with an acetone solution (4 ml) of (2E)-[5-<sup>14</sup>C]methoprene at 0.01 ppm and the other flask at 0.50 ppm (5.0 mCi/mmol for 0.01 ppm; 0.88 mCi/mmol for 0.50 ppm). The flasks were fitted with a series of traps for the collection of <sup>14</sup>CO<sub>2</sub>. Air passing into the flasks was first passed through soda lime (to remove atmospheric CO<sub>2</sub>) and then rehydrated (5% potassium hydroxide). The air entered the flask and then exited into two traps containing KOH (5%, 200 ml). The flasks were exposed to di-

rect sunlight (through ca. 2 mm Pyrex) for 3 weeks (July 11-Aug 2, 1973). The temperature of aqueous photolysis was monitored with a Tempacrite temperature recorder (Bacharach Instrument Co.). Average high temperatures are given in Table I. The weather was sunny with minimal smog. Aliquots (1 ml) from the KOH traps were counted in Insta-Gel (Packard) periodically to measure evolution of <sup>14</sup>CO<sub>2</sub>. Aliquots (100 ml) of the aqueous photolysate were extracted with chloroform (3  $\times$  75 ml) to follow the rate of methoprene photodecomposition (Table II). After 3 weeks the aqueous solutions of photoproducts were still aseptic as determined by culturing an aliquot (0.5 ml) on nutrient agar for 3 days.

The radioactivity collected in KOH traps was verified as <sup>14</sup>CO<sub>2</sub> by precipitation as Ba<sup>14</sup>CO<sub>3</sub>. A solution (60 ml) of BaCl<sub>2</sub> (0.4 N) and NH<sub>4</sub>Cl (0.5 N) was added to the KOH solution (100 ml). The mixture was cooled in ice for 1 hr and then filtered through pre-weighed glass fiber paper; the white precipitate was washed with acetone. After drying and weighing, the precipitate was suspended in Insta-Gel (10 ml) and water (4 ml) for quantitation of radioactivity. An aliquot (1 ml) of the filtrate was also counted to determine the amount of unprecipitated radioactivity. This procedure gave a 71% yield of Ba<sup>14</sup>CO<sub>3</sub>. Another sample of KOH (100 ml) was acidified with HCl and purged of <sup>14</sup>CO<sub>2</sub> by adding Dry Ice while stirring. An aliquot (1 ml) was then counted to authenticate the removal of <sup>14</sup>CO<sub>2</sub>. Ninety-three per cent of the radioactivity was removed from the KOH solution by this process, thus confirming the identity of <sup>14</sup>CO<sub>2</sub>.

**Aqueous Emulsion Photolysis. Isolation of Photoproducts.** An aqueous emulsion of methoprene was irradiated in a 6-l. erlenmeyer flask (sunshine, April 4-11, 1974) to isolate photoproducts. A hard-water emulsion of methoprene was prepared with the following composition: methoprene (2  $\times$  10<sup>7</sup> dpm, 400 mg), CaCl<sub>2</sub> (1.2 g), MgCl<sub>2</sub>·6H<sub>2</sub>O (0.56 g), Atlox 3404F (200 mg, ICI America), Atlox 847 (200 mg), and autoclaved water (4 l.). After irradiation for 1 week (sunlight through Pyrex), the entire photolysate was poured onto a column of Amberlite XAD-2 (Eastman, 4  $\times$  11 cm). The effluent water contained little radioactivity (9%). Methanol (500 ml) eluted 83% of radioactivity and acetone (300 ml) eluted 4% of the radioactive photoproducts. Thus, 96% of the applied radioactivity was accountable. The methanol and acetone eluates were resolved into component photoproducts by tlc (silica gel GF, Merck, four 0.2  $\times$  1 m plates; developed in benzene-ethyl acetate-acetic acid, 100:30:3). Because of the plethora of products further purification by tlc was also necessary. Photoproducts were characterized by nmr, ir, and glc-ms and showed spectral coincidence with reference standards.

The most abundant product (*R<sub>f</sub>* 0.56, 9%) was 7-methoxycitronellal (2) which was isolated as its dimethyl acetal. Authentic dimethyl acetal (3) was prepared in

Zoecon Corporation Research Laboratory, Palo Alto, California 94304.



quantitative yield by stirring citronellal (58 mg) in methanol (2 ml) containing *p*-toluenesulfonic acid (47 mg); nmr (CDCl<sub>3</sub>)  $\delta$  0.91 (d, 3,  $J$  = 6 Hz, C-3 CH<sub>3</sub>), 1.15 (s, 6, geminal CH<sub>3</sub>), 1.33 (br s, 9), 3.19 (s, 3, OCH<sub>3</sub>), 3.33 (s, 6, acetal OCH<sub>3</sub>), 4.48 (t, 1,  $J$  = 6 Hz, CH(OCH<sub>3</sub>)<sub>2</sub>); ir (CDCl<sub>3</sub>) no C=O; mass spectrum  $m/e$  (rel intensity), no molecular ion, 185 (2), 169 (5), 153 (2), 137 (13), 95 (11), 85 (14), 81 (22), 75 (90), 73 (100).

Methoxycitronellal (4,  $R_f$  0.39) was isolated in 7% yield. It has been characterized from metabolic studies of methoprene (Schooley *et al.*, 1975).

Isopropyl (2*E*)-4,5-epoxy-11-methoxy-3,7,11-trimethyl-2-dodecenoate (5,  $R_f$  0.72) was recovered in 4% yield. An authentic standard was prepared in 49% yield by stirring methoprene (104 mg) with *m*-chloroperbenzoic acid (90 mg) in methylene chloride for 18 hr at room temperature: nmr (CDCl<sub>3</sub>)  $\delta$  0.97 (d, 3,  $J$  = 6 Hz, C-7 CH<sub>3</sub>), 1.16 (s, 6, geminal CH<sub>3</sub>), 1.28 (d, 6,  $J$  = 7 Hz, CH(CH<sub>3</sub>)<sub>2</sub>), 1.37 (m, 9), 2.09 (d, 3,  $J$  = 2 Hz, C-3 CH<sub>3</sub>), 2.85 (t, 1,  $J$  = 7 Hz, H-5), 3.11 (br s, 1, H-4), 3.20 (s, 3, OCH<sub>3</sub>), 5.08 (m, 1,  $J$  = 7 Hz, OCH(CH<sub>3</sub>)<sub>2</sub>), 5.93 (s, 1, H-2); ir (CDCl<sub>3</sub>) 1700 cm<sup>-1</sup> (C=O); mass spectrum,  $m/e$  (rel intensity), no molecular ion, 207 (2), 98 (52), 95 (11), 81 (8), 73 (100).

8-Methoxy-4,8-dimethyl-2-nonanone (6,  $R_f$  0.63) was isolated in 4% yield. An authentic sample was prepared in quantitative yield by treating methoxycitronellal with excess methylmagnesium bromide and oxidizing the resultant alcohol with acidic chromium trioxide in acetone: nmr (CDCl<sub>3</sub>)  $\delta$  0.92 (d, 3,  $J$  = 6 Hz, C-4 CH<sub>3</sub>), 1.17 (s, 6, geminal CH<sub>3</sub>), 1.35 (m, 7), 2.15 (s, 3, COCH<sub>3</sub>), 2.32 (m, 2, COCH<sub>2</sub>), 3.20 (s, 3, OCH<sub>3</sub>); ir (CDCl<sub>3</sub>) 1705 cm<sup>-1</sup> (C=O); mass spectrum,  $m/e$  (rel intensity), no molecular ion, 185 (2), 153 (3), 111 (5), 109 (6), 95 (10), 73 (100).

After 1 week of exposure to sunshine no methoprene was detectable from the aqueous emulsion. There were at least 46 other photoproducts but none was present in greater than 2% yield. A control showed no significant thermal decomposition at 40° in the dark.

**Thin Film Photodecomposition on Glass.** In order to measure the rate of photodecomposition on Pyrex glass, methoprene (3.1 mg, 0.15 mCi/mmol) was dissolved in acetone (20 ml) and uniformly coated on the walls (300 cm<sup>2</sup>) of a 500-ml round-bottomed flask by solvent removal on a rotary evaporator. The application rate corresponds to 11  $\mu$ g/cm<sup>2</sup> (1 lb/acre) and a film thickness of 0.1  $\mu$ . Other flasks of methoprene films were prepared in the same manner. The flasks were exposed to sunshine (Oct 5-7, 1973) with periodic removal for product assay. After addition of methanol, photoproducts were analyzed for total radioactivity and amount of methoprene (Table II).

Volatilized methoprene and photoproducts were collected in a gas trap (250 ml) containing a glass wool plug and immersed in a Dry Ice-acetone bath. Radioactive carbon dioxide was collected in two 5% potassium hydroxide traps (200 ml) connected to the outlet of the Dry Ice trap. After 6 days the methoprene (0.2%) and methoxycitronellal (4.0%) collected in the cold trap were characterized by tlc and glc. The contents of the KOH traps were verified as <sup>14</sup>CO<sub>2</sub> as described above. Acidification of the trapped radioactivity in KOH followed by purging of <sup>14</sup>CO<sub>2</sub> with Dry Ice liberated 83% of the <sup>14</sup>C label. Only a 14% loss of radioactivity accompanied the acidification-purging process for products collected in the cold trap; thus, little <sup>14</sup>CO<sub>2</sub> was collected in the Dry Ice-acetone trap.

Thin film photoproducts were isolated after irradiation on glass. Methoprene (75 mg, 0.025 mCi/mmol) was dissolved in acetone (20 ml) and uniformly dispersed on the inner walls (1060 cm<sup>2</sup>) of two 2-l. round-bottomed flasks. This application rate corresponds to 35  $\mu$ g/cm<sup>2</sup> (3 lb/acre, 0.4- $\mu$  film thickness). The flasks were stoppered with glass wool-plugs and exposed to direct sunlight (though ca. 2 mm Pyrex) for 4 days (Nov 1-4, 1973) during warm, clear

weather. After 4 days, photoproducts in the flasks (94% of applied dose) were removed with methanol. The photolysate was preparatively fractionated by tlc on silica gel (hexane-ethyl acetate, 2:1) into six radioactive regions. The most nonpolar radioactive region ( $R_f$  0.70) was identified as methoprene (7% of applied dose). Also isolated were methoxycitronellal (4,  $R_f$  0.28, 4% yield), the epoxide 5 ( $R_f$  0.64, 6%), and the methyl ketone 6 ( $R_f$  0.42, 3%). There were at least 50 other photoproducts but none accounted for more than 4% yield.

**Sensitized Thin Film Photodecomposition on Silica Gel.** Anthraquinone (20  $\mu$ g) and Rose Bengal (20  $\mu$ g) were added to separate tlc plates (silica gel GF, Analtech, 5 x 20 cm, 250  $\mu$ ). Methoprene (4  $\mu$ g, 5.0 mCi/mmol) was dissolved in benzene and spotted on the sensitizers. Duplicates of each plate and controls with methoprene (but without sensitizer) were exposed to direct sunlight. After 1, 6, and 7 hr photoproducts were characterized by tlc (hexane-ethyl acetate, 100:15) and the distribution of photoproducts is summarized in Table IV. Radioactivity was recovered quantitatively and structures confirmed by glc.

**Sensitized Methanolic Photolysis.** Methoprene (290 mg, 0.94 mmol, 7.2  $\mu$ Ci/mmol), Rose Bengal (80 mg), and methanol (1 l.) were added to a Pyrex immersion cell. Oxygen was bubbled through the solution while stirring magnetically. The dilute solution was irradiated with a tungsten-halogen lamp (500 W, 120 V, Sylvania) for 4 days. Solvent was evaporated and the products isolated by tlc on silica gel (four 20 x 20 cm plates). The majority of the photolysate was unreacted (2*E*,4*E*)-methoprene (47%) and the 2*Z*,4*E* isomer 12 (30%).

A single major photoproduct was characterized as isopropyl 2,5-epoxy-2-hydroxy-11-methoxy-3,7,11-trimethyl-3-dodecenoate (7) which was isolated in 12% yield and characterized as follows: nmr (CDCl<sub>3</sub>)  $\delta$  0.93 (d, 3,  $J$  = 6 Hz, CH<sub>3</sub>), 1.15 (s, 6, geminal CH<sub>3</sub>), 1.30 (d, 6,  $J$  = 7 Hz, OCH(CH<sub>3</sub>)<sub>2</sub>), 1.70 (t, 3,  $J$  = 1 Hz, -CCH<sub>3</sub>), 3.20 (s, 3, OCH<sub>3</sub>), 5.18 (m, 2, OCH(CH<sub>3</sub>)<sub>2</sub> and H-5), 5.87 (s, 1, H-4); ir (CDCl<sub>3</sub>) 3490 (OH), 1720 cm<sup>-1</sup> (C=O); mass spectrum,  $m/e$  (rel intensity) after silylation with Regisil (Regis Co.), no molecular ion, 294 (20), 250 (11), 235 (19), 207 (10), 167 (18), 166 (26), 140 (14), 139 (14), 73 (100); uv  $\lambda_{max}$  202 nm ( $\epsilon$  3900, cyclohexane). A structural isomer of 7 with the hydroxyl group at the 5 position in the dihydrofuran was excluded because the nmr spectrum lacked a methine singlet.

When 7 was treated with methanolic sodium hydroxide (0.1 M) it was converted in 45% yield into 6-(6-methoxy-2,6-dimethylheptyl)-3-hydroxy-4-methyl-2-pyrone (8): nmr (CDCl<sub>3</sub>)  $\delta$  0.90 (d, 3,  $J$  = 6 Hz, CH<sub>3</sub>), 1.16 (s, 6, geminal CH<sub>3</sub>), 2.11 (s, 3, C-4 CH<sub>3</sub>), 3.10 (s, 3, OCH<sub>3</sub>), 5.86 (s, 1, H-5); ir (CDCl<sub>3</sub>) cm<sup>-1</sup> 3470 (OH), 1670 (C=O), 1660, 1580 (C=C); mass spectrum,  $m/e$  (rel intensity), 282 (1), 267 (13), 251 (12), 206 (9), 166 (13), 140 (12), 139 (8), 100 (12), 73 (100); uv  $\lambda_{max}$  296 ( $\epsilon$  6900, cyclohexane).

Methoprene was stable under the same photolysis conditions without Rose Bengal or when oxygenated in methanol (<2% decomposition after 2 days). When a 0.3 M methanolic solution of methoprene was exposed to sunlight through 2-mm Pyrex glass for 25 days, only 10% of 1 had decomposed.

## RESULTS AND DISCUSSION

**Aqueous Photodecomposition.** Before attempting to isolate and characterize the aqueous photooxidation products of methoprene (1), it was necessary to assess the magnitude of photolability. Therefore, an aqueous solution of 1 was exposed to sunlight through Pyrex glass, and the rate of decomposition was measured. Methoprene was rapidly decomposed in aqueous solutions of 0.5 ppm (Table I) and 0.01 ppm. The half-life of 1 at both concen-



Table I. Rate of Methoprene Photodecomposition in Aqueous Solution (0.5 ppm)

Day	% $^{14}\text{C}$ in water	% methoprene recovd	Extraction with $\text{CHCl}_3$			Temp (av daily high), $^{\circ}\text{C}$	Total $^{14}\text{C}$ recovd
			% $^{14}\text{C}$ in $\text{CHCl}_3$	% $^{14}\text{C}$ in aq phase	$^{14}\text{CO}_2$ /% $^{14}\text{C}$ in KOH trap		
0	100	96	100	0	0.0	39	100
1	98	23	87	13	0.0	39	96
3	97	17	82	18	0.2	37	97
7	92	12	81	19	0.9	36	93
14	93	1	78	25	2.2	40	95
21	91	0	70	30	3.4		94

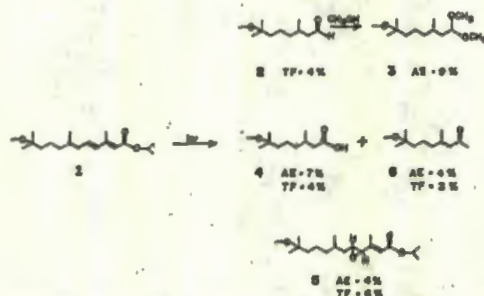


Figure 1. Photoproducts of methoprene from irradiation of an aqueous emulsion (AE) and thin film (TF) on glass.

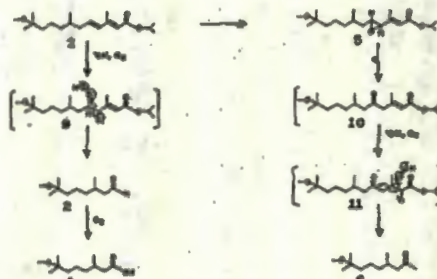


Figure 2. Possible mechanism for formation of photoproducts (cf. Swern, 1970).

trations was apparently less than 1 day although in related studies (Schooley *et al.*, 1976) a half-life of 4-5 days was found. While the initial decomposition of 1 was extremely facile in this experiment, after 1 week 12 and 5% of the applied methoprene remained in the 0.5- and 0.01-ppm solutions, respectively. After 2 weeks there was no detectable methoprene. The rate of aqueous photodecomposition of 1 in this experiment was similar for 0.5- and 0.01-ppm solutions although somewhat faster at the more dilute concentration as expected. Total radioactivity in the aqueous photolysate was 91% of the applied dose after 3 weeks (Table I). An additional 3% was characterized as radioactive carbon dioxide which represented extensive decomposition in order to liberate C-5 in methoprene as  $^{14}\text{CO}_2$ . However, with 94% of the total radioactivity recovered, loss of photoproducts by volatility was minor for the aqueous photodecomposition.

Since methoprene has limited water solubility (1.4 mg/l.), it was difficult to amass enough of each photoproduct for detailed spectral analysis (*i.e.*, nmr). Attempts were made to identify milligram quantities of five photoproducts produced in aqueous solution. These were characterized as oxygenation products, presumably involving the dienoate moiety. Four of the products (11, 13, 7.5, and 13% of the applied dose) could be acylated while the major product (25%) could not be acylated, methylated, or reduced ( $\text{NaBH}_4$ ), but each of these products contained the ester and ether moieties present in the parent compound. However, no positive identifications of these substances were made. Several of these aqueous solution photoproducts appeared to be either impure or isomeric mixtures from nmr, and the mass spectra were singularly uninformative. Fragmentations of the tertiary methyl ether moiety of methoprene and its derivatives (*i.e.*, photoproducts and metabolites) so dominate the mass spectra that relatively little information can be derived regarding modifications to the dienoate moiety (Dunham *et al.*, 1973).

Indications of thermal instability of several photoproducts were found on glc-ms analysis.

The laborious isolation of minute amounts of products from copious quantities of water was circumvented by irradiation of an aqueous emulsion of methoprene (see Experimental Section). By photooxidizing a larger mass of emulsified methoprene (400 mg) it was considerably easier to purify enough material for spectral characterization. However, the distribution of photoproducts in the aqueous emulsion of methoprene was not identical with the profile of aqueous solution products.

After an aqueous emulsion of methoprene was irradiated for 1 week by sunlight through Pyrex glass followed by methanol chromatographic work-up, four photoproducts (24% yield overall) were characterized (Figure 1) as methoxycitronellal dimethyl acetal (3, 9%), methoxycitronellal (2, 7%), an epoxide of methoprene (5, 4%), and a methyl ketone (6, 4%). Unreacted methoprene was not detectable and there were at least 46 other photoproducts but none represented more than 2% yield.

The most predominant photolytic pathway involved formation of methoxycitronellal (2) and its subsequent oxidation to the corresponding acid 4. Methoxycitronellal (2) was isolated as its dimethyl acetal (3), which was undoubtedly an artifact of the isolation procedure.

Mechanistically, the formation of the aldehyde 2 (Figure 2) may involve initial peroxidation of the 4-ene double bond to give 9 (cf. Swern, 1970) which may undergo cleavage to give 2. Cleavage of similar peroxides to aldehydes has been reported (Gollnick, 1968). Air oxidation of the aldehyde 2 to the acid 4 occurs readily by autoxidation. A total of at least 16% of the methoprene was photolyzed by this or a similar pathway.

The epoxide 5 and methyl ketone 6 were produced by the operation of different mechanisms. Epoxidation of olefins is a well-known reaction even for otherwise unreactive olefinic pesticides (Crosby, 1973) although the mechanism



Table II. Rate of Methoprene Photodecomposition as Thin Film on Glass

Exposure to sun, hr	Methoprene recovd, % applied dose	Total radioact. recovd, % applied dose
0	97	100
3	79	100
6	50	100
12	29	95
27	3	72

Table III. Collection of Volatile Photoproducts from Methoprene Photolyzed as Thin Film on Glass

Day	2, % yield	1, % yield	% radioact. in cold trap*	% radioact. in KOH trap,* <sup>14</sup> CO <sub>2</sub>
1			0.4	
4	3.6	0.2	5.0	
5			6.7	
6	4.0	0.2	7.6	5.6

\* Expressed as per cent applied dose.

is poorly understood. Formation of the 4,5-epoxide (5) follows from the greater reactivity of the 4-ene double bond than the 2-ene bond toward electrophilic peracids. Epoxidation of the 2-ene double bond is considerably slower, but can be accomplished with peracids under more drastic conditions (e.g., higher temperature). Hydration of the epoxide 5 to the diol was not detectable in contrast to a report on the photooxidation of another IGR (Gill *et al.*, 1974). Formation of the methyl ketone 6 necessarily involved several steps. Rearrangement of the epoxide 5 would give the keto ester 10 (Figure 2). Subsequent peroxidation of 10 to 11 followed by scission of 11 would yield the methyl ketone 6. The postulated intermediates (i.e., 9, 10, and 11) could not be isolated from the crude photolysate.

**Thin Film Photodecomposition.** Methoprene was rapidly degraded when a thin film (0.1  $\mu$ ) on glass was exposed to sunlight through glass (Table II). The half-life for photochemical breakdown under these conditions was 6 hr. After exposure to sunlight for 27 hr, only 3% of the applied dose remained as methoprene and it was isomerized to a 50:50 mixture of (2E,4E)- and (2Z,4E)-methoprene. The recovery of only 72% of the applied radioactivity after 27 hr suggested photolysis of methoprene to volatile products which were lost by vaporization. Collection of vapors above the photolysate resulted in recovery of 13% of the applied radioactivity (Table III). The volatile constituents were resolved into methoxycitronellal (2, 4%), methoprene (1, 0.2%), and <sup>14</sup>CO<sub>2</sub> (6%). Since only a trace of methoprene (0.2%) was isolable from condensed vapors, volatility of methoprene was not a major route for loss of radioactivity.

Resolution of the crude photolysate after exposure of methoprene to sunshine for 4 days gave methoxycitronellal (4, 4%), the epoxide 5 (6%), the methyl ketone 6 (3%), and methoprene (7%, equal mixture of 2E and 2Z). There were also at least 60 other photoproducts, but none represented more than 4% yield. The production of photoproducts is summarized in Figure 1.

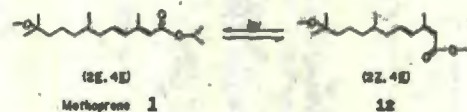


Figure 3. Photoisomerization of methoprene.

Table IV. Photoproducts from Photosensitized Decomposition of Methoprene on Silica Gel

	Time, (1) hr	% methoprene remaining (2)	% methoxycitronellal (3)	% other products
Control	1	91	2	4
(no sensitizer)	6	76	14	9
Rose Bengal	1	85		11
sensitized	6	44	3	31
Anthraquinone	1	71		12
sensitized	6	14	6	73

The 2,4-dienoate chromophore of methoprene was quite susceptible to photoisomerization of the 2-ene double bond (Figure 3). (2E,4E)-Methoprene was readily isomerized to the 2Z,4E isomer 12 under most conditions (i.e., as thin film or in solution) after exposure to light (cf. Henrick *et al.*, 1975b). Biological 2,4-dienoic metabolites (Quistad *et al.*, 1974) and all field samples of aqueous methoprene (Schaefer and Dupras, 1973) contained substantial amounts of 2Z isomers. Photoisomerization of the 2-ene double bond drastically reduces the biological potency of methoprene, since the 2Z isomer 12 is 1000 $\times$  less active on *Aedes* mosquito larvae (Henrick *et al.*, 1975a). The 4-ene double bond is photochemically stable. Similar photoisomerization (50%) of the 2-ene double bond and stability of the 4-ene double bond has been observed for the 2Z,4E-dienoic chromophore in abscisic acid (Bonnafous *et al.*, 1973).

**Photosensitized Decomposition.** Organic photosensitizers often accelerate photochemical reactions. The abundance of natural sensitizers (e.g., chlorophyll) justifies the inclusion of photosensitizers in a study of the environmental photodecomposition of methoprene. Two photosensitizers with different triplet energies ( $E_T$ ) were selected to examine breakdown of methoprene on silica gel. Anthraquinone ( $E_T$  = 62 kcal/mol) was chosen because it was most effective in sensitizing decomposition of many pesticides (Ivie and Casida, 1971) and Rose Bengal ( $E_T$  = 42 kcal/mol) because it sensitizes the efficient production of singlet oxygen (at least in solution).

The effect of photosensitizers was observed for methoprene photodecomposition on silica gel plates. Both Rose Bengal and anthraquinone increased the rate of photocatalyzed breakdown of methoprene. The profile of products was similar to the thin film photodecomposition of methoprene on glass in exhibiting a multitude of components. Anthraquinone was more effective than Rose Bengal in this experiment (86% vs. 56% decomposition of methoprene in 6 hr) in sensitizing photodegradation (Table IV). The most prevalent product (10-14%) was methoxycitronellal (2) for the unsensitized photodecomposition on silica gel from the control (no added sensitizer). The formation of 2 was predominately photocatalyzed and not thermal since methoprene on silica gel in the dark at 40 $^\circ$  gave only a 1-2% yield of 2. The sensitizers diverted the photo-



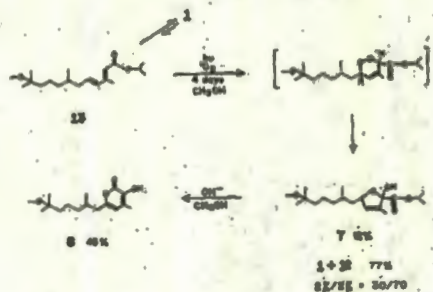


Figure 4. Methanolic photooxidation of methoprene, reaction with singlet oxygen.

chemical breakdown of methoprene from 2 to other pathways and also complicated the product distribution (Table IV). The rate of 2-ene isomerization was considerably slower on silica gel than in solution. After 7 hr exposure to sunlight on silica gel, methoprene was 36% isomerized [Z:E, 36:64] at the 2-ene bond whereas in aqueous solution the same amount of isomerization occurred in 2 hr.

Methoprene was very stable to photodecomposition in methanol. Without added sensitizer a solution of methoprene showed only 10% decomposition after 25 days in methanol. A dilute methanolic solution of methoprene with Rose Bengal sensitizer was also quite stable. After 4 days of photosensitized oxygenation 47% of the original (2E,4E)-methoprene was unreacted and 30% of the 2Z isomer 12 was formed (cf. Henrick *et al.*, 1975b). A single major photoproduct (12%) was characterized as the dihydrofuranol 7. An isomer of 7 with the hydroxyl group in the 5 position was also structurally consistent with the spectral data except for multiple coupling of the methine proton in the nmr spectrum. The 2-hydroxydihydrofuran 7 should also be favored mechanistically by preferential removal of the methine proton adjacent to the carbonyl in the intermediate cyclic peroxide (Figure 4). Analogous hemiketals have been reported from the addition of singlet oxygen to other dienes (Mousseron-Canet *et al.*, 1967). The addition of singlet oxygen to methoprene was slow and appeared to follow the mechanism given in Figure 4. A 1,4-cycloaddition of singlet oxygen to the s-cis-diene conformation of methoprene (13) could give the un-

stable cyclic peroxide which could collapse to the dihydrofuranol 7. Treatment of this hemiketal with base gave a 45% yield of the hydroxypyrene 8. The addition of singlet oxygen to the related 2,4-dienoate hydroxyprone has previously been shown to give the analogous hydroxypyrene although the dihydrofuranol was identified spectrally as an intermediate (Henrick *et al.*, 1975b). Neither the dihydrofuranol 7 nor hydroxypyrene 8 could be identified as aqueous or thin film photoproducts of methoprene.

Methoprene is very susceptible to photolytic decomposition under environmental conditions. It is degraded to a plethora of photoproducts which are present in relatively low yield (<10%). The rapid degradation of methoprene and multiplicity of photolytic products are indicative of extensive photodegradability in the natural environment.

#### ACKNOWLEDGMENT

We especially thank B. J. Bergot for work on aqueous decomposition and L. L. Dunham, R. Veit, and B. Meyers for glc and glc-ms analysis. We thank R. Curtis for formulating the aqueous emulsion and for useful discussions we thank C. A. Henrick and J. B. Siddall.

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## POND TESTS WITH ZR-515: BIOLOGICAL AND CHEMICAL RESIDUES

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**INTRODUCTION.** In a previous report (Schaefer and Wilder 1972) we demonstrated that the developmental inhibitor ZR-515 (isopropyl 11-methoxy-3, 7, 11-trimethyl-2, 4-dodecadien-8-ate) had the potential of controlling OP-resistant *Aedes nigromaculis* larvae under field conditions, at rates as low as 1/8 lb/A. However, the applications had to be carefully timed so that medium to late 4th stage larvae were treated; the residues following application of ZR-515 EC (emulsifiable concentrate) were not sufficient to control earlier stage larvae. During 1972, further studies showed that when EC applications were very carefully timed (against late 4th stage larvae) doses as low as 1/8 lb/A were highly effective against field populations; it was also quite apparent that such treatments were not effective when mixed or earlier aged populations were the target (Schaefer and Wilder 1973). It was obvious that such critical timing of treatments would not allow for operational feasibility. Recognizing that ZR-515 had high inherent biological activity against *A. nigromaculis* we sought to find formulations that would offer longer residual activity.

**METHODS AND RESULTS.** Numerous formulations were evaluated during 1972 that had no apparent increase in residual biological activity as compared to the EC. However, one formulation was found that showed real promise; this was a 10% flowable liquid, slow-release formulation, which was composed of microencapsulated particles containing ZR-515 in a water base. On July 1, 1972 a pond was treated with this formulation at a dose of 0.35 lb AI/A (AI = active ingredient). The bioassay results are given in Table 1.

Table 1. Bioassay of pond water treated with 0.35 lb AI/A of 10% flowable liquid formulation of ZR-515.

Sampling time (days after treatment):	0 <sup>1</sup>	1	2	3	4	5
Bioassay results (% mortality) <sup>2</sup>	100	97	80	75	17	5

<sup>1</sup> Immediately after treatment.

<sup>2</sup> In percent inhibition of adult emergence of 4th-stage *Culex pipiens quinquefasciatus* larvae added and reared in the laboratory.

Based on these findings, we then conducted extensive tests using this 10% flowable liquid formulation, by hand sprayer and by aircraft, on field populations of OP-resistant *A. nigromaculis* larvae. Tests in both the San Joaquin and Sacramento valleys showed that this formulation could achieve practical control of mixed-stage populations of *A.*

*nigromaculis* and good results were obtained at doses down to 1/40 lb AI/A (Schaefer and Wilder 1973).

Since it appeared that this formulation would provide a practical tool for controlling *A. nigromaculis* populations, cooperative tests were made with the personnel of the U. S. Bureau of Sports Fisheries and Wildlife at the Kern Research Area (20 miles west of Delano, California). Formulations were supplied by Zuecon Corporation. The ponds (30 ft x 60 ft x 1 ft) were treated at a rate which appeared likely for the operational control of mosquito larvae (.05 lb AI/A) and at 5 and 10 times this rate. Two formulations were tested at each rate: (1) the 10% flowable liquid described above, and (2) a 5% flowable liquid similar to the 10% except that the microencapsulated particles contained a 1:1 mixture of ZR-515 and Tenox®, a commercial antioxidant. The test formulations were mixed with approximately 2/3 gallon of water in a hand sprayer and applied to a given test pond. Applications were made at early morning hours before wind drift was significant. Shortly after treatment and at 24-hour intervals thereafter, a water sample was taken along the north and the south borders of the control and treated ponds; these were bioassayed with *Culex pipiens quinquefasciatus* larvae by procedures previously described (Schaefer and Wilder 1972).

The results of bioassaying pond water immediately after treatment and then at daily intervals for 3 days is shown in Table 2; it appears that the Tenox formulation offered more residual activity on the third day at all 3 doses. These results were very encouraging since a high degree of biological activity continued for a 3-day period. Also, the bioassay

Table 2. Bioassay of water from treated ponds with 4th-stage *Culex pipiens quinquefasciatus* larvae (in % inhibition of adult emergence).

Formulation	Dose (lb AI/A)	Sampling time (days after treat.)			
		0	1	2	3
10% Std. <sup>1</sup>	.05	100	49	62	0
5% T. <sup>2</sup>	.05	100	40	40	32
10% Std.	.25	100	82	100	46
5% T.	.25	100	91	100	59
10% Std.	.50	100	86	100	49
5% T.	.50	100	82	100	73

<sup>1</sup> 10% flowable liquid composed of microencapsulated particles containing ZR-515 in a water base.

<sup>2</sup> 5% flowable liquid composed of microencapsulated particles containing a 1:1 mixture of ZR-515 and Tenox in a water base.



Table 3.—Residues (ppm) of ZR-515 in pond water of the Kern Research Area ponds as determined by gas-liquid chromatography.

Formulation	Dose (lb AI/A)	Sampling time (hours after treatment)									
		2		12		24		48		72	
		north	south	north	south	north	south	north	south	north	south
10% Std. <sup>1</sup>	.05	.076	.046	.010	.023	.007	.006				
5% T. <sup>2</sup>	.05	.056	.075	.014	.017	.008	.008				
10% Std.	.25	.199	.395	.058	.030	.018	.018	.008	.010	.009	.008
5% T.	.25	.260	.279	.056	.083	.026	.036	.013	.012	.009	.011
10% Std.	.50	.320	.544	.080	.103	.028	.025	.010	.022	.010	.010
5% T.	.50	.204	.296	.084	.190	.052	.034	.025	.018	.011	.009

<sup>1</sup> 10% flowable liquid composed of microencapsulated particles containing ZR-515 in a water base.

<sup>2</sup> 5% flowable liquid composed of microencapsulated particles containing a 1:1 mixt mixture of ZR-515 and Tenox in a water base.

was done using *C. p. quinquefasciatus* larvae, which are much more tolerant to ZR-515 than are *A. nigromaculata*.

For chemical analysis, 600 ml water samples were taken from the upper 2 inches, along the north and south borders of the control and treated ponds; these were extracted in a field laboratory adjacent to the ponds and the extracts were transported to the Fresno Laboratory for quantitative analyses by gas-liquid chromatography. Details of this procedure have been described (Schaefer and Dupras 1973).

The chemical residues are shown in Table 3. At 2 and 12 hours following treatment, 5 of the 6 treated ponds showed higher amounts of ZR-515 along the south border, which was the lee side; but this difference does not appear to exist at 48 or 72 hours. The chemical data does not show a greater concentration of ZR-515 in the 5% Tenox treated ponds (as compared to the 10% standard formulation) at 72 hours, or 3 days, as indicated by the bioassay data (Table 2). Further comparisons of these formulations seem necessary.

The chemical and biological assays of the treated ponds show a steady and rather rapid depletion of ZR-515 from the water; this indicates that ZR-515 dissipates quickly and

is a favorable attribute in relation to current concerns relative to environmental pollution resulting from pesticide use. Other chemical residue studies conducted during 1972 have given similar results (Schaefer and Dupras 1973).

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Insect Developmental Inhibitors. 4. Persistence of ZR-515 in Water<sup>1</sup>

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## ABSTRACT

Residues of ZR-515 (isopropyl 11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate) were greatly affected by sunlight and temperature. The technical ZR-515 tended to remain on the water surface, and its distribution was affected by wind. The half-life of technical ZR-515 or an EC

formulation in field water was only about two hours. Treatments of 10 percent flowable liquid (slow release) formulation in water showed almost no detectable residues by chemical analysis after 24 hours, although biological activity persisted for several days.

Using bioassay methods (Part 1, Schaefer and Wilder 1972), it was shown that the biological activity of aqueous solutions of ZR-515 (isopropyl 11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate) were affected by sunlight, temperature, and microbial action. Unfortunately there was not a clear-cut linear relationship between percent mortality and concentration, therefore the bioassay method was not quantitative. In conjunction with Parts 2 and 3 of this series (Schaefer and Wilder 1973, Miura and Takahashi 1973), the persistence of ZR-515 was measured by quantitative chemical analysis. These studies are presented here.

**MATERIALS AND METHODS.—Formulations Studied.**—Initial stability determinations were made using a technical grade liquid which was composed of 70% *trans* (biologically active) and 20% *cis* (biologically inactive) isomers and 10% of impurities. All expressions of concentrations, doses, or rates are based on the content of *trans* isomer. Field trials were made using the 4.0 lb AI/gal EC and the 10% flowable liquid (slow release) formulation previously discussed (Schaefer and Wilder 1973) and in one case technical material was used.

**Determination of ZR-515 in Water.**—The methods used were slightly modified from a procedure developed by Miller et al. 1973, based on the Mills et al. (1963) method of determining chlorinated pesticide residues in nonfatty foods. Technical ZR-515 was dissolved in acetone, and 0.5 ml of various concentrations were added to 600 ml of water to give the desired initial concentration. At the selected time of extraction, 200 ml of redistilled acetonitrile was added, the combined solution was poured into a 1000-ml separatory funnel and partitioned against 100 ml of petroleum ether. The petroleum ether phase was dried over Na<sub>2</sub>SO<sub>4</sub>, concentrated in a rotoevaporator to about 0.5 ml, and then transferred into a graduated tube for gas-liquid chromatographic analysis. The latter was accomplished using a 1/4-in. diam and 6-ft long Pyrex column packed with 3% OV101 on 100/120 mesh Chromosorb W-AW-DMCS. A Hewlett-Packard Model 5750 gas chromatograph equipped with a hydrogen flame ionization detector was used. The column temperature was 180°, the injection port 190°, and the detector 330°C. The carrier gas was helium, and the flow rate was 60 ml/min.

**Stability of ZR-515 in Water-Acetonitrile.**—To determine how long samples of treated water, e.g. field samples, could be held before extraction into organic solvents was required (to prevent change in the ZR-515 content), we conducted a series of experiments. Duplicate sets of 600 ml water aliquots in 1000-ml beakers were treated with 0.1 ppm of the various formulations

just described; 200 ml of acetonitrile was immediately added to each container, and sets were partitioned into petroleum ether immediately and at posttreatment intervals of 4, 24, and 48 h and then analyzed as described earlier.

**Recovery of ZR-515 from Water.**—To determine the efficiency of the analytical method for extracting ZR-515 from water, duplicate sets of 1000-ml beakers containing 600 ml of tap, pasture, pond, or sewage lagoon water were treated at 0.10, 0.05, and 0.01 ppm with acetone solutions of technical ZR-515 and then immediately analyzed as described. In addition, a triplicate set of tap water samples was treated at 0.001 ppm and similarly analyzed.

**Effects of Sunlight on Persistence of ZR-515 Aqueous Solutions.**—Duplicate sets of 1000-ml beakers containing 600 ml of tap water were treated at 0.1 ppm with acetone solutions of technical ZR-515 and held in direct sunlight on a hot (38°C max ambient temperature), clear day. Sets were extracted and analyzed immediately and at 4, 8, and 24 h following treatment.

**Effects of Temperature on Persistence of ZR-515 Aqueous Solutions.**—Duplicate sets of 1000-ml beakers (without covers) containing 600 ml of tap water each and a similar set containing distilled water were treated with an acetone solution of technical ZR-515 to give 0.1 ppm. The beakers were held in the dark in temperature-controlled cabinets at 10°, 24°, and 38°C, and duplicate sets from each temperature and water type were extracted and analyzed at 24, 48, 72, 96, and 120 h after treatment. Control sets of each water type were analyzed immediately after treatment.

Also, on a hot (39°C max ambient temperature), clear day a duplicate set of 1000-ml beakers containing 600 ml of tap water each was placed in a water bath (which was held at 12±2°C) outside in direct sunlight beside a 2nd similar set which was not cooled. All beakers were treated at 7:00 AM with acetone solutions of technical ZR-515 to give 0.1 ppm and then held outside for 8 h, then they were extracted and analyzed. The water temperatures of a control set of untreated, uncooled, and cooled beakers were recorded every 30 min.

**Distribution of Technical ZR-515 in Water.**—Since ZR-515 technical material has the properties of an oil, it was important to determine its distribution following water treatment to understand how field water samples should be collected. Three thousand ml of water was placed in a 4L beaker and treated with an acetone solution of technical ZR-515 to give a 0.1 ppm concn. After allowing the treated water to stand for 30 min, 100-ml samples were pipetted from the surface, the middle, and the lower part of the beaker; these were extracted and analyzed as described earlier.

<sup>1</sup> Received for publication Jan. 20, 1973.  
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Table 1.—Recovery of ZR-515 from different types of water.

Type of water	Concentration (ppm)		
	0.10	0.05	0.01
Tap	0.105	0.051	0.0095
	.105	.051	.0097
Pasture	.096	.057	.0097
	.102	.056	.0096
Pond	.099	.056	.011
	.100	.050	.010
Sewage	.101	.050	.0097
	.100	.051	.0091

**Sampling of Treated Water in Field Tests.**—White enamel dippers (about 450-ml capacity) with 4-ft handles were used to collect water in the treated field areas from the upper 2 in of the water surface (reasons for this will be given later). For each sample, a total of 600 ml was collected into a 1000-ml stoppered graduated cylinder by accumulating dips of about 150–200 ml each. If the 600-ml mark was overfilled, the total amount of the sample was recorded, but excess amounts were never poured out. A separate dipper was used for each differently treated and control area, and dippers were washed before being used for sampling at later times. After each 600-ml water sample was collected, 200 ml of acetonitrile was added immediately, and the graduate was then stoppered and shaken. When treatment had been made using either the technical or the EC formulation, the stoppered graduates were transported back to the laboratory for extraction and analysis. However, for treatments where the 10% flowable slow-release formulations had been used, it was necessary to partition the ZR-515 into petroleum ether as soon as possible (reasons to be explained later). Extractions under field conditions were done in a small mobile laboratory.

**Field Applications of ZR-515 Formulations.**—The applications of the EC and 10% flowable, slow-release formulations by hand sprayer or aircraft were as described in Part 2 (Schaefer and Wilder 1973). The stability of technical ZR-515 in pond water was studied following application with a hand sprayer of 7.6 g of technical material in 0.75 gal of hexane to a pond (29 × 58 ft × 12 in.) to give an initial rate of 0.3 lb AI/acre.

**RESULTS AND DISCUSSION.—Recovery of ZR-515 from Water.**—Table 1 shows the recoveries of ZR-515 from tap, pasture, pond, and sewage lagoon waters at the 3 concentrations shown. Since water quality had no apparent effect on recovery, only tap water was spiked with 0.001 ppm; 3 samples treated at this level showed recoveries of 0.0011, 0.0011, and 0.0012 ppm. Using the 600-ml sample size and procedures described, we were able to estimate the amount of ZR-515 down to a level of 0.0003 ppm. However, we consider as rough estimates amounts determined to be less than 0.001 ppm.

**Stability of ZR-515 in Water Acetonitrile.**—When water samples were spiked at 0.1 ppm and acetonitrile was added immediately and the solution was mixed, there was no apparent loss of ZR-515 after 4, 24, or 48 h of standing time. Thus field water which had been treated with a total-release formulation, e.g., technical material or emulsifiable concentrate could be stabilized

with acetonitrile for reasonable periods to allow transport and extraction at the home laboratory. However, when the microencapsulated (10% flowable, slow release) formulation was used to spike water samples at 0.1 ppm, immediate partitioning of the water-acetonitrile mixture into petroleum ether showed 60% recovery (0.06 ppm). This value increased with increased standing times before making the partition. Thus, the acetonitrile extracted ZR-515 from the microencapsulated particles and the sooner the partition into petroleum ether was made, the greater the accuracy of measurement of ZR-515 in the water phase. Even a short exposure of the microencapsulated particles to acetonitrile would likely cause some extraction of ZR-515 from the capsules and therefore this method would most likely give erroneously higher values. As no better procedure was available, the immediate-extraction method just described was used for the 1972 studies.

**Effect of Sunlight on Persistence of ZR-515 Aqueous Solutions.**—When 1000-ml beakers containing 600 ml of tap water and spiked with 0.1 ppm ZR-515 were held in direct summer sunlight, only 13% of the initial concentration was present after 4 h and only 2% after 8 h; none was detectable at 24 h (<0.0003 ppm). Thus, the rate of loss is very rapid and supports our previous report (Schaefer and Wilder 1972) that sunlight reduces the biological activity of ZR-515.

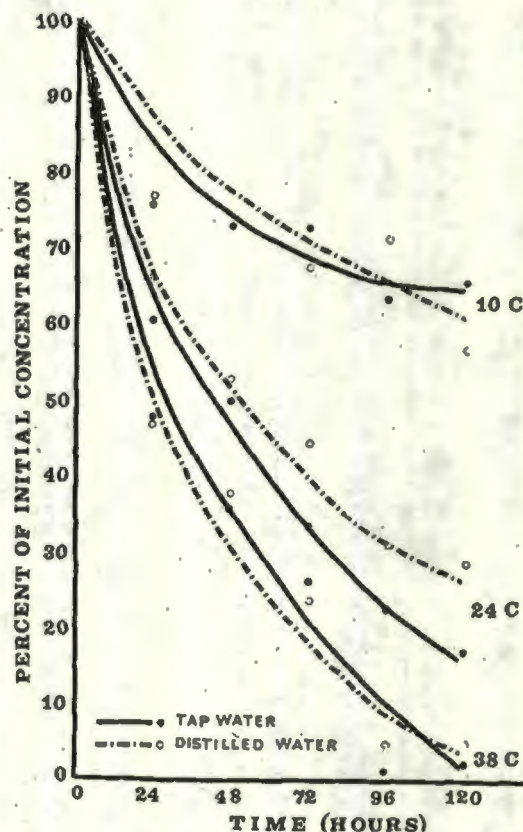


Fig. 1.—Effect of temperature on the persistence of ZR-515 in aqueous solutions.



Table 2.—Residues of ZR-515 (ppm) in individual field water samples.

Field test no.	Date (1972)	Formulation and habitat	Rate (lb AI/acre)	Sample collection time <sup>a</sup>					
				0	4	8	24	48	72
1	5/8	EC pond	0.1	0.34 .06 .31	b	—	ND <sup>c</sup> ND ND	—	—
2	5/31	EC pond	.1	.32 .06 .74	0.02 .01	0.0054 .0040	0.0017 .0017	ND ND	—
3	5/31	EC pond	.3	.44 .09 1.06	.06 .04 .05	.02 .01 .02	.0017 .0009 .0009	ND ND ND	—
14	7/11	Tech. pond	.3	1.50 1.23 .40	1.23 .06 .02	—	.0018 .0016 .0018	ND ND ND	—
33	8/30	10%F <sup>d</sup> pasture	.1	.062 .033 .022	—	—	ND ND ND	ND ND ND	ND ND ND
				.043 .096 .033			ND ND ND	ND ND ND	ND ND ND
37 <sup>e</sup>	9/12	70%F pasture	.05	.015 .030	—	—	ND ND	—	ND ND
38	9/15	10%F duck club	.1	.26			.003	ND	ND

<sup>a</sup> In hours after treatment.<sup>b</sup> Indicates no samples were collected.<sup>c</sup> ND = not detected (<0.0003 ppm).<sup>d</sup> 10% flowable liquid (slow release).<sup>e</sup> Samples in these tests were analyzed by Stoner Laboratories, Campbell, Calif. The reported detection limit was 0.001 ppm.

It is also noteworthy that while the *trans* isomer of ZR-515 composes 70% of the technical material (20% *cis*), when aqueous solutions were exposed to sunlight there was isomerization to a 1-1 ratio between the *cis* and *trans* forms. This ratio was always observed when analyzing water samples containing ZR-515 that had been exposed to sunlight.

**Effect of Temperature on Persistence of ZR-515 Aqueous Solutions.**—The effect of increased temperature on ZR-515 in solution is apparent in Fig. 1; there did not appear to be any significant difference as a result of water quality. When duplicate sets of beakers were placed outside in direct sunlight on a hot summer day, the set that was cooled to 12±2°C averaged 21% of the initial concentration after 8 h, but the uncooled set, for which the water temperature reached 39°C during the experiment, averaged only 1.3% after the same exposure. Thus, temperature had a definite effect, but sunlight appeared to be a much more important factor accounting for the rapid decline in concentration.

**Distribution of Technical ZR-515 in Water.**—When the water samples taken from the surface, middle, and lower part of the treated water in a 4L beaker were analyzed, the surface concn was 1.50 ppm, 0.05 for the middle and 0.02 for the lower portion. Thus, the compound tended to move to the water surface. For this reason, collections of water from treated fields were made from within 2 in. of the upper surface.

**Analysis of ZR-515 in Water Following Field Treatment.**—Table 2 shows the residues of ZR-515 in treated waters. The rapid loss of ZR-515 from water is apparent and agrees with the studies reported here. The large variation between samples collected immediately after treatment (0 h) indicated that the material was not yet evenly dispersed. This was particularly true follow-

ing applications of the technical material in hexane (F.T. no. 14) where the higher concentration occurred on the lee side of the pond (an oil slick was apparent there for several hours). The latter also indicated that a large amount of the ZR-515 applied tended to stay on the surface and did not distribute greatly into the body of water. The 10% flowable liquid formulation showed little residual at 24 h or longer following treatment, but bioassay data showed that small amounts, sufficient to control mosquito larvae, persisted for several days (Schaefer and Wilder 1972, Schaefer et al. 1973).

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## Occurrence of Trifluralin and Its Photoproducts in Air

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Trifluralin vapor photodecomposed to a number of products in a laboratory vapor-phase reactor which simulated sunlight conditions. For analysis, an air sampling method utilizing a coated solid adsorbent as a vapor trap was developed which trapped these materials at air flow rates greater than 1 m<sup>3</sup>/min and with a limit of detectability of less than 1 ng/m<sup>3</sup>. Trifluralin and sev-

eral photoproducts were detected in the air above both surface treated and soil incorporated fields. These photoproducts probably arise primarily from photolysis of trifluralin on the soil surface followed by volatilization; however, the contribution of vapor-phase photolysis of trifluralin undoubtedly increases with increasing air residence time.

Photodecomposition is often one of the primary modes of environmental dissipation of chemicals, and the breakdown of many pesticides under sunlight conditions has been demonstrated both on solid surfaces and in water. Recently, attention has been given to photolysis in another environmental compartment—the atmosphere. For example, the vapor-phase photolyses of aldrin and dieldrin (Crosby and Moilanen, 1974) and DDT (Moilanen and Crosby, 1973) in a laboratory photoreactor were recently reported. The present study was undertaken to investigate the possible occurrence of this process under actual field conditions.

Trifluralin (2,6-dinitro-*N,N*-dipropyl- $\alpha,\alpha,\alpha$ -trifluoro-*p*-toluidine) (I), a widely used preemergence herbicide, was selected as a study model. The manufacturer generally recommends immediate soil incorporation since three to four times as much trifluralin is needed for equal efficacy when applied as a surface spray. This led to early speculation that trifluralin may undergo volatilization and/or photodecomposition in the field. In fact, both of these processes occur: Wright and Warren (1965) showed that trifluralin decomposed in sunlight on glass plates or soil surfaces, and Crosby and Leitis (1973) identified a number of photoproducts formed during irradiation at sunlight wavelengths in water. The relatively high vapor pressure ( $2.42 \times 10^{-4}$  Torr at 30°; Spencer *et al.*, 1973) is manifested by significant vapor loss from soil, the rate being a function of soil moisture content among other factors (Bardley *et al.*, 1968; Ketchersaid *et al.*, 1969; Parochetti and Hein, 1973; Spencer *et al.*, 1973).

In the present study, the vapor-phase photolysis of trifluralin in a laboratory reactor was examined; a novel method utilizing a coated solid adsorbent was developed to trap trifluralin and its photoproducts from air; and, finally, field tests were conducted to assess the extent to which these photoproducts occur in the atmosphere above treated soil.

## EXPERIMENTAL SECTION

**Chemicals.** Technical trifluralin (95%) (Eli Lilly and Co., Indianapolis, Ind.) was recrystallized from absolute ethanol to a mp of 48° (48.5–49°, Probst *et al.*, 1967). 2,6-Dinitro-*N*-propyl- $\alpha,\alpha,\alpha$ -trifluoro-*p*-toluidine (II), 2,6-dinitro- $\alpha,\alpha,\alpha$ -trifluoro-*p*-toluidine (III), 2-ethyl-7-nitro-1-propyl-5-trifluoromethylbenzimidazole (IV), and 2-ethyl-7-nitro-5-trifluoromethylbenzimidazole (V) were synthesized according to the procedures of Leitis and Crosby (1974). All solvents were distilled twice in glass prior to use.

**Vapor-Phase Photolysis.** The vapor-phase photoreactor and light source were described previously (Crosby and Moilanen, 1974). Trifluralin (5 mg) was dissolved in

2–3 ml of hexane, the solution placed on a 48-cm watch glass, and the solvent evaporated in a current of air to leave a thin solid film. The dry watch glass was placed at the bottom of the reactor chamber and warmed to 35° to enhance volatilization.

After several hours, during which the trifluralin vaporized in the chamber, irradiation was commenced. Photolysis proceeded for up to 12 days at 25–30°, after which the reactor was dismantled and rinsed with four 500-ml portions of hexane and two 500-ml portions of acetone. The combined rinses were concentrated to a small volume and subjected to thin-layer chromatography (tlc) (0.5-mm silica gel G containing 1% zinc orthosilicate-phosphor, developed in hexane-acetone, 3:1). The resulting bands were detected by fluorescence quenching with 254-nm light and visual observation, scraped off, eluted with warm acetone, and quantitated by gas chromatography-mass spectrometry (gc-ms). A Finnegan Model 3000 peak identifier equipped with a 1.5 m  $\times$  3 mm (i.d.) glass column containing 2% OV-1 on 60–80 mesh Chromosorb G was employed. The column temperature was programmed from 150 to 270° at 10°/min; injector and detector temperatures were both 240°, and the carrier gas (helium) flow rate was 16 ml/min. As each compound eluted, its mass spectrum was recorded and identified by comparison with that of an authentic specimen.

A simultaneous experiment was conducted in an identical reactor except that the light trap was replaced with a spherical reflector (Crosby and Moilanen, 1974); a dark control was included in yet another flask. All experiments were analyzed in an identical manner.

**Photolysis of Trifluralin on Coated Dust.** Light from an RS sunlamp (Crosby and Moilanen, 1974) was directed horizontally through a 5-l. round-bottomed flask attached with a 24/40 ground-glass joint to a rotary evaporator motor (Calab Co., Oakland, Calif.). Standardized Air Cleaner Test Dust, Fine (Air Filter Testing Labs, Inc., Louisville, Ky.) was coated to 20 ppm by the addition of I in a small volume of diethyl ether followed by drying at ambient temperature, and 0.25 g placed inside the flask. The standard dust was mainly (91  $\pm$  3%) in the 0–40  $\mu$  range and contained 1.3% organic matter and 1.0% moisture. Rotation of the flask about the horizontal axis effectively suspended a portion of the coated dust in the light beam. After irradiation for 1–15 hr, the dust and flask were rinsed with two 10-ml portions of acetone. Trifluralin was quantitated by electron-capture gas chromatography as described later. An identical experiment conducted in the absence of light served as a dark control.

**Air Sampling Equipment.** Air sampling for trifluralin vapors above treated fields was conducted with two types of apparatus. A commercial Hivolume Sampler (Figure 1; Natural Environmental Instruments, Inc., Fall River, Mass.), fitted with an 8 in.  $\times$  10 in. glass fiber filter (Reeve Angel Co., Clifton, N.J.) and charged with 30 g of

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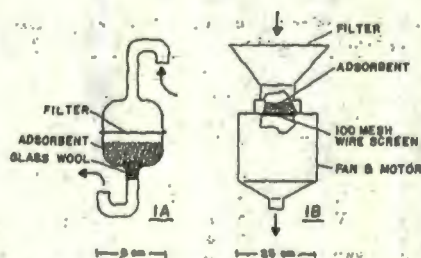


Figure 1. Schematic representations of the Lovol (A) and Hivol (B) Samplers. Scale indicates approximate size.

adsorbent, processed about one cubic meter of air per minute. Low-volume sampling was carried out using an Air Sampling Assembly (Microchemical Specialties Co., Berkeley, Calif.) modified as follows. The filter cup was charged with 30 g of adsorbent held in place with glass wool at the bottom and a glass fiber filter at top (Figure 1A), covered with aluminum foil, mounted on a 5 cm diameter  $\times$  4 m vertical pipe, and connected to the pump assembly with vacuum tubing. It processed about 0.03 m<sup>3</sup> of air per min. The liquid impingers were not used. These traps are referred to as the Hivol and Lovol Samplers in the subsequent discussion.

The adsorbent was 20-30 mesh Chromosorb A (Applied Science Labs, Ingleswood, Calif.) purified by Soxhlet extraction with acetone overnight and then coated to 5% (w/w) with paraffin oil previously purified by extraction in succession with concentrated sulfuric acid, water, and acetonitrile.

**Analytical Methods.** *Chromatography.* Gas-liquid chromatography (glc) was carried out with a Varian Model 2100 gas chromatograph equipped with a 1.8 m  $\times$  2 mm (i.d.) glass column containing 5% OV-17 on 80-80 mesh Chromosorb G and a tritium electron capture detector. Column, injector, and detector temperatures were 180, 225, and 215°, respectively; carrier gas (nitrogen) flow rate was 25 ml/min. Thin-layer chromatography (tlc) was carried out on 20 cm  $\times$  20 cm, 0.25 mm thick Anasil GF silica gel plates (Analabs Inc.) developed with hexane.

*Air Samples.* A sealed 250-ml erlenmeyer flask containing the adsorbent from a sampler and 100 ml of acetone was agitated with rotary shaking for 1 hr. The acetone was decanted and filtered through Whatman No. 1 paper. Additional acetone (50 ml) was swirled with the adsorbent, decanted, and filtered. The combined filtrates were adjusted to 100 ml, and a 50-ml aliquot was concentrated to 2 ml and analyzed for trifluralin by glc.

Another aliquot (25 ml) was concentrated in a 15-ml centrifuge tube until only paraffin oil remained; the residue was chilled in ice and twice extracted with 1 ml of cold acetone by vortex stirring followed by centrifugation. The combined acetone extracts were concentrated and the acetone extraction repeated, if necessary, until a volume convenient for spotting on a tlc plate (0.1-0.2 ml) was attained. Samples were run alongside enough trifluralin standard for visual confirmation of its  $R_f$  value. After development in hexane, the silica gel between the origin and the  $R_f$  of trifluralin was scraped off and eluted with acetone. The acetone was concentrated to about 0.1 ml and analyzed for photoproducts II-V by glc.

The Hivol glass fiber filters were placed in a 250-ml erlenmeyer flask with 100 ml of acetone and agitated on a rotary shaker for 1 hr. The acetone was decanted, filtered through Whatman No. 1 paper, concentrated to an appropriate volume, and analyzed for I by glc.

*Soil Samples.* Composite soil samples were mixed thor-

oughly without adjustment of the moisture content and analyzed by a modification of the procedure of Smith (1972): a 20-g sample was weighed into a 125-ml erlenmeyer flask, 50 ml of benzene and 25 ml of 2-propanol were added, the flask was sealed, and the mixture was agitated for 30 min on a rotary shaker. After settling, two 25-ml aliquots were each rinsed twice with 15-ml portions of 3% aqueous sodium chloride to remove the 2-propanol. The benzene was dried briefly with anhydrous sodium sulfate, analyzed for I, and then subjected to tlc as described above for analysis of II-V. Acetone was used to extract soil samples too wet to be extracted with benzene-2-propanol with equivalent results. Limits of detectability for I-V were about 0.01 ppm. Soil moisture content was determined by overnight drying (110°) of an accurately weighed 1-2-g sample followed by cooling and reweighing.

**Field Experiments.** In one experiment, a 15 m  $\times$  15 m bare soil plot at the University of California, Davis, was disced to a depth of 0.15 m and surface treated (1.7 kg/ha of I) with Treflan emulsifiable concentrate (Elanco Products Co., Indianapolis, Ind.) without soil incorporation in June, 1973. The field was sprinkler irrigated with water to a depth of 3 cm 2.8 days after application to enhance the volatilization of trifluralin. Lovol Samplers were mounted on a pipe tower in the center of the plot at 0.5 and 1.8 m above ground, a Hivol Sampler was placed 0.5 m above ground, and a portable weather station which monitored temperature, relative humidity, and wind conditions was located adjacent to the plot.

Air samples were collected immediately after, and for 7 days following, trifluralin application. Each Lovol Sampler was run during daylight for about 10 hr (about 18 m<sup>3</sup> of air sampled) and the Hivol Sampler for about 3 hr (about 180 m<sup>3</sup> of air sampled). Adsorbent was removed on the following morning into foil covered flasks and returned to the lab, 100 ml of acetone was added, and the mixture was stored at -10° until processed. Soil core samples (2.5 cm  $\times$  7.5 cm deep) were collected daily from 20 random locations within the plot, composited, and stored at -10° in foil-lined bags.

A second experiment was performed whereby Treflan was soil incorporated to a depth of 15 cm. A 61-ha field in Sutter County, Calif., was disced repeatedly, treated with Treflan (0.8 kg/ha of I), disced twice again, and planted in safflower in April 1974. The Hivol Sampler was run daily for 4 hr during midafternoon near the center of the field. Air and soil samples were processed as described above, except that emphasis was given to the determination of I and II.

These two experiments will be referred to as the surface treatment and soil incorporation experiments in subsequent discussion.

## RESULTS AND DISCUSSION

**Laboratory Photolysis.** The photoreactor was designed so that a light beam shining through the substrate vapor would not intercept the walls, except at the end of the flask where a small window allowed light to exit into a light trap. Alternatively, wall irradiation, and hence surface-induced photoreactions, could be promoted by replacing the light trap with a spherical reflector (Crosby and Moilanen, 1974). Irradiation of trifluralin in the reactor under normal conditions (i.e., with the light trap) resulted in conversion to a number of products, and reflection of light onto the reactor wall produced no discernible change in the amount or nature of photoproducts. Trifluralin vapor was stable in the dark.

The dinitrotoluidines II and III, benzimidazoles IV and V, and benzimidazole precursors VI, VII, VIII, and IX reported by Leitis and Crosby (1974) were detected (Figure 2). Short term irradiation produced primarily II while longer irradiation (12 days) resulted mainly in IV and V



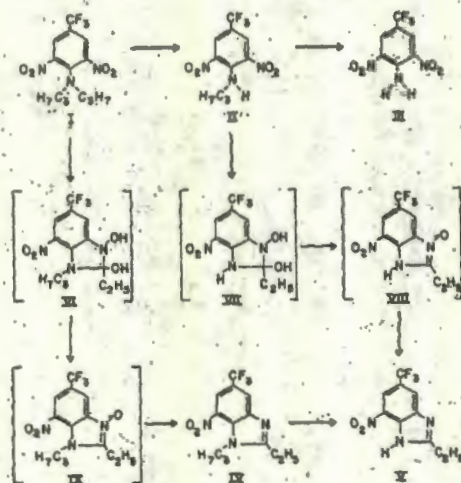


Figure 2. Proposed vapor-phase photolysis pathway of trifluralin (I).

Table I. Vapor-Phase Photoproducts of Trifluralin

Compound	$R_f$ value <sup>a</sup>	Amount, mg <sup>a</sup>
I	0.80	0.7
II	0.52	0.3
III	0.40	0.1
IV	0.39	2.1
V	0.23	1.7

<sup>a</sup> Amount found after irradiation of 5 mg of I for 12 days. <sup>b</sup> Silica gel G (0.5 mm) developed in hexane-acetone (3:1).

(Table I). Irradiation of IV resulted in its facile conversion to V which was resistant to further photolysis. All of the volatile photoproducts were identified by comparing their  $R_f$  values, retention times, and mass spectra with those of authentic standards. In addition to the volatile products, a highly colored (orange-brown) band remained at the origin of the tic plate. Characterization of this band following elution with warm methanol employed a thermal degradation method (Leitis and Crosby, 1974) in which the eluted material was subjected to glc analysis. The resulting pattern of three peaks indicated the presence of the benzimidazole precursors reported by Leitis and Crosby (1974) (Figure 2): 2,3-dihydroxy-2-ethyl-7-nitro-1-propyl-5-trifluoromethylbenzimidazole (VI); 2,3-dihydroxy-2-ethyl-7-nitro-5-trifluoromethylbenzimidazole (VII); 2-ethyl-7-nitro-5-trifluoromethylbenzimidazole-3-oxide (VIII); and 2-ethyl-7-nitro-1-propyl-5-trifluoromethylbenzimidazole 3-oxide (IX).

The vapor-phase photolysis of trifluralin involves both oxidative dealkylation and cyclization. Photochemical N-dealkylation of amines appears to be a free-radical oxidation by atmospheric oxygen (Sharkey and Mochel, 1969). Benzimidazole formation, reported by Crosby and Molanen (1972) and Crosby and Leitis (1973), has been confirmed for similar dinitroaniline herbicides (Newsom and Woods, 1973; Plimmer and Klingebiel, 1974; Niles and Zabik, 1974). These cyclization reactions may be accounted for (Leitis and Crosby, 1974) by a modification of the free-radical mechanism proposed by Doepp (1971) to explain the photochemical formation of indole N-oxides

Table II. Trapping Efficiencies for Trifluralin and Its Photoproducts from Air<sup>a</sup>

Compd	Recovery, %	
	1.0 $\mu\text{g}^c$	25 $\mu\text{g}^c$
I	40 $\pm$ 7	48 $\pm$ 4
II	36 $\pm$ 4	61 $\pm$ 10
III	49 $\pm$ 8	67 $\pm$ 11
IV	85 $\pm$ 10	91 $\pm$ 10
V	84 $\pm$ 5	101 $\pm$ 5

<sup>a</sup> Air at 20° (125 m<sup>2</sup>) processed with Hivol sampler. <sup>b</sup> Average and standard deviation of three determinations. <sup>c</sup> Amount introduced onto the filter.

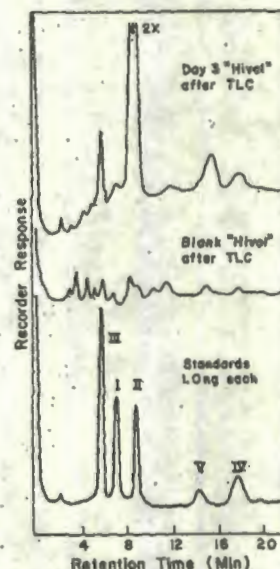


Figure 3. Typical chromatograms of a sample, blank, and standard compounds I-V.

from nitroaralkanes. The proposed mechanism is consistent with vapor-phase conditions, since it represents light-induced polarization of the nitro group and subsequent intramolecular rearrangements which do not require external reagent. Photolysis in I in the absence of oxygen produced exclusively IV.

Photolysis of trifluralin films, solutions, and coated soils was also carried out. For example, the irradiation of suspended dust coated with I gave results essentially identical (half-life of 2.6 hr at 20 ppm on standard test dust) with those obtained by irradiation of I on soil in a Petri dish (half-life of 2.2 hr at 60 ppm on Dinuba fine sandy loam soil). In general, it appears that I decomposes faster in solution, as a thin film on glass, and when adsorbed to soil or suspended dust than as a vapor, although difficulties inherent in measuring the rate of vapor-phase photolysis have precluded confirmation of this view.

Trifluralin and photoproducts II-IV are all photolabile; V, however, appears to resist further photolysis. For example, irradiation of V at 20 ppm on suspended standard test dust for 3 hr resulted in its quantitative recovery. Prolonged irradiation (200 hr) of V in the vapor-phase



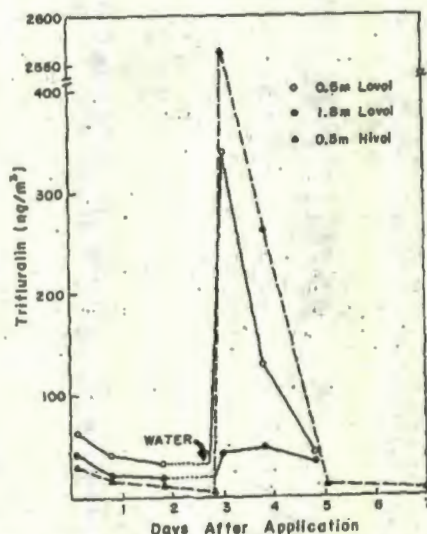


Figure 4. Trifluralin concentrations in air over a surface treatment plot.

photoresactor confirmed that V should be considered a photochemically stable product.

**Air Sampling Techniques.** Air sampling techniques for pesticides usually consist of drawing air through a solvent-filled bubbler or impinger (Miles *et al.*, 1970). Drawbacks to this method include a restricted sampling rate (0.03 m<sup>3</sup>/min) which necessitates long sampling periods, and expensive and fragile glassware often inconvenient for portable use. Solid trapping agents offer an alternative to liquid absorption methods (Seiber and Woodrow, 1974). The system adopted for the trifluralin studies utilized a filter bed consisting of Chromosorb A coated to 5% with paraffin oil, although several other solid trapping agents were effective. Trapping efficiencies for vapors of trifluralin and its photoproducts (determined by spiking the Hivol filter with known amounts of I-V and measuring the percent of the vaporized material trapped on the solid after 2 hr of sampling) were adequate and reproducible (Table II). Furthermore, extraction recoveries of I-V (2 µg) from the adsorbent exceeded 85%. For analysis of photoproducts II-V, the large excess of I was conveniently removed from air sample extracts by preparative tlc. The chromatograms of Figure 3 illustrate typical results. From the glc response of standards relative to air blanks, the usual detection limits of I-V were calculated to be 0.5-1.0 ng/m<sup>3</sup>.

**Surface Treatment Plot.** Following the completion of the laboratory photolyses and method development, several experiments were carried out to check for the presence of I and its breakdown products in the field. In one experiment, I was applied to the surface of bare soil with no incorporation. Although this condition does not reflect application practice recommended by the manufacturer, it afforded enhanced volatilization for the quantitation of I-V in the air. Volatilization was further enhanced by overhead irrigation 2.8 days after application. Samplers placed in the center of the plot indicated concentrations of I of less than 61 ng/m<sup>3</sup> for the initial 2.8 days before the dramatic effect of soil moisture on the volatilization rate of I occurred (Figure 4). The concentration of I measured by the Hivol Sampler on day 3 exceeded that of the

Table III. Photoproducts in Air (Surface Treatment, Hivol, Day 3)

Compd	Amt, ng/m <sup>3</sup>
I	2570
II	12.4
III	0.73
IV	≤0.50
V	≤0.50

Table IV. Soil Residues from Surface Treatment

Days after application	Soil residue, ppm <sup>a</sup>				
	I	II	III	IV	V
1	2.03	0.060	0.005	0.048	0.027
2.7	1.18	0.096	0.014	0.037	0.080
7	0.45	0.067	0.010	0.020	0.028

<sup>a</sup> Averages of three determinations with relative deviations of 14%.

Lovel Samplers (Figure 4) since the Lovel values are an average of 10 hr of sampling, the latter portion of which probably contained much less trifluralin than immediately after water application. The Hivol sample on the other hand is an average of only the first 2 hr after water application when trifluralin volatilization was at its maximum. Trifluralin was still vaporizing after 7 days, but at a lower rate than for the 0-2.8 day period.

Analysis of the day 3 Hivol sample for photoproducts (Table III) showed the unmistakable presence of II, and III, while the benzimidazoles IV and V were tentatively identified at levels near their detection limit. These results conform to the laboratory model in which II was the initial product, while prolonged irradiation (12 days) yielded primarily IV and V. Since the atmospheric residence time of I before reaching the sampler undoubtedly was quite brief, little localized formation of V was expected or found. The possibility that II-V originated from impurities in the herbicide formulation was precluded by careful analysis of a sample taken directly from the spray tank. Possible degradation of I to II-V on the adsorbent surface was ruled out by their absence from a sample of Chromosorb A spiked with I and used to sample clean air for 2 hr.

Analysis of soil samples showed that residues of I declined from 2.03 to 0.45 ppm in 7 days (Table IV). Photoproducts appeared in the first sample (0.1 day), increased slightly at day 2.7, and declined by day 7. The existence of "polar products" (Probst *et al.*, 1967) and the tentative identification of polar azoxy derivatives (Leitis, 1973) argue for the existence of other breakdown pathways in addition to photolysis; microbial action probably played a minor role, since I was not incorporated and the soil was extremely dry except during and just after irrigation. Probst *et al.* (1967) concluded that while microorganisms may contribute to the eventual destruction of trifluralin, this cannot be considered a major pathway of degradation.

**Soil Incorporation Plot.** While the surface treatment experiment was successful in proving the existence of I and some of its photoproducts in air, a similar evaluation under more realistic conditions was clearly desirable. Thus, in a second field experiment, I was soil incorporated into a larger area (61 ha).

This time, concentrations of I in the air measured by Hivol Sampler (Figure 5) declined from 12 ng/m<sup>3</sup> to less than 1 ng/m<sup>3</sup> within 3 days. A heavy rain (0.37 in.) on



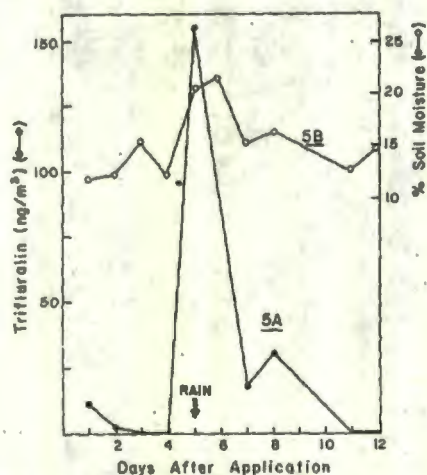


Figure 5. Trifluralin concentrations in air (A) and per cent soil moisture (B) for a soil incorporated field.

day 5, and again between days 7 and 8, increased air levels as in the previous experiment. While the overall appearance of Figure 5A matches Figure 4, the maximum values are significantly less in the former, indicating the less drastic effect of water on soil incorporated I. Comparison of concentrations of I to the soil moisture plot (Figure 5B) reemphasizes the correlation between the volatilization rate of I and soil moisture content. A summary of the results of the second experiment is presented in Table V; the presence of II in the air was confirmed by gc-ms analysis of pooled samples 5, 6, and 8, the mass spectrum and retention time being identical with those of II. The fact that I was incorporated to a depth of 15 cm while the soil was sampled to a depth of only 7.5 cm, coupled with the movement of I to the soil surface by moisture, accounts for the trend of increasing concentrations of I in soil with time (Table V).

**Source of Photoproducts.** While some trifluralin photoproducts (e.g., II) unquestionably were present in the air after both surface treatment and soil incorporation of I, their origin is not as clear. Three potential routes of

photoproduct formation must be considered: (1) via photolysis of I vapors in the atmosphere; (2) via photolysis of I on the soil surface followed by volatilization; and (3) via photolysis of I on air-suspended dust. The importance of these routes depends not only on the relative photolysis rates at the appropriate sites, but on transport to the sites as well. For example, the volatilization rate of I from soil into the atmosphere may limit the importance of route 1 more than the rate of vapor-phase photolysis. Since route 3 would significantly contribute to the disappearance of I only in cases of very dry soil and appreciable wind, attention will be focused on the other possibilities with specific reference to the formation of II.

Evidence to support the formation of II on soil surfaces (route 2) derives from the laboratory photolysis of I on soil (and on suspended dust) and detection of II in the soil immediately after both surface and soil incorporated application of I in the field. If this route were to predominate, the ratios of II to I in air and soil would be identical after correction for their relative volatilities. If route 1 was significant, the ratio of II to I in the air should exceed that in soil; however, the ratios of II to I in soil and air (soil incorporation experiment, Table V) were essentially identical. The soil ratio ideally should be determined on a sample taken from the top few millimeters of soil where II would be formed; however, the fact that soil was sampled to a depth of 7.5 cm further decreases the significance of route 1 in these experiments.

Nevertheless, vapor-phase photolysis remains undeniable. To confirm the laboratory results, I (5 g) was vaporized directly into a field atmosphere from an electrically heated glass tube (5 cm o.d.  $\times$  20 cm) by means of a blower within 25 m of a Hivol Sampler placed 1 m above ground. The sampler was run for 15 min while I was being vaporized; analysis indicated 0.55% breakdown of I to II (0.52  $\mu$ g of II and 94  $\mu$ g of I trapped) while the unvaporized solid remaining in the tube contained undetectable (less than 0.1%) II as an impurity.

The above field-test data indicate that route 2—photolysis of I at the soil surface followed by volatilization—must predominate. However, while the direct-vaporization experiment shows vapor-phase photolysis to occur at an appreciable rate, the air samples were collected so close to the ground that I vapor would have had only brief residence in the atmosphere. As a major proportion of the trifluralin lost from the soil moves as vapor (Parochetti and Hein, 1973; Savage and Barrentine, 1969), the atmosphere must provide a significant repository in which trifluralin eventually is degraded until only photochemically stable products remain.

Table V. Summary of the Soil Incorporation Experiment

Days after application	Weather conditions; wind <sup>a</sup> & air temp, °C	Air samples <sup>b</sup>				Soil samples		
		I, ng/m <sup>3</sup>	II, ng/m <sup>3</sup>	II/I, %	I on filter, $\mu$ g	I, ppm	II, ppm	II/I, %
1	Light; 23	11.7	0.42	3.6	0.45	0.48	0.017	3.5
2	Heavy; 25	2.7			1.10	0.42	0.014	
3	None; 27	<1			0.23	0.52	0.024	
4	Heavy; 24	<1			0.22	0.65	0.021	
5	Heavy; (rain)	155	4.9	3.1	0.28	0.65	0.030	4.6
6	Heavy; 15	91.4	2.4	2.6	0.18	0.52	0.027	5.3
7	Light; 20	17.4	0.44	2.5	0.32	0.88	0.021	2.4
8	Light; 15	31.3	1.0	3.2	0.40	0.71	0.017	2.4
11	Heavy; 31	<1			0.35	0.70	0.026	
12	Moderate; 28	<1				0.45	0.024	

Av 3.0%

Av 3.6%

<sup>a</sup> Light = 0-5 mph; moderate = 5-10 mph; heavy = >10 mph. <sup>b</sup> Single determinations. <sup>c</sup> Averages of three determinations with relative deviations of 13%.



## ACKNOWLEDGMENT

We thank Floyd Colbert (Eli Lilly Co.), Erika Leitia, and Clayton Reese for technical assistance with aspects of this research.

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Received for review September 3, 1974. Accepted November 18, 1974. Presented at the Division of Pesticide Chemistry, 167th National Meeting of the American Chemical Society, Los Angeles, Calif., April 1974. Supported in part by National Science Foundation Grant No. GB-33723X and by Eli Lilly and Company.

## Fate of Pyrazon in a Model Ecosystem

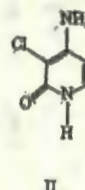
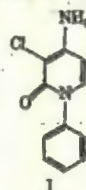
Ching-Chieh Yu,<sup>1,2</sup> Gary M. Booth,<sup>3</sup> Dale J. Hansen,<sup>3</sup> and Joseph R. Larsen<sup>4</sup>

Pyridazinone ring-<sup>14</sup>C-labeled pyrazon [5-amino-4-chloro-2-phenyl-3(2H)-pyridazinone] was slowly degraded in water. Thirty-two days after application of the compound to a model ecosystem, about 68% of the radioactivity in the water was found to be the parent compound. Very small amounts of 2-dephenylpyrazon [5-amino-4-chloro-3(2H)-pyridazinone] and five other unknown spots (combined total 1%) were detected only after acid hydrolysis. The remainder of the radioactivity was present as unextractable water-

soluble products (33%). Combined parent compound and metabolites in organisms living in the ecosystem ranged from 0.06 ppm in fish to 0.6 ppm in crab. Analysis of the crab extracts revealed that no 2-dephenylpyrazon was present and that the parent pyrazon constituted about 76% of the total radioactivity in that organism. There was no evidence to indicate that pyrazon and its degradation products were magnified through the food chain.

Pyrazon, 5-amino-4-chloro-2-phenyl-3(2H)-pyridazinone (I), is a selective herbicide used in red beet and sugar beet production (Fischer, 1962). Metabolism of this compound in plants and soil has been investigated (Frank and Switzer, 1969a,b; Ries *et al.*, 1968; Smith and Meggitt, 1970a,b; Stephenson and Ries, 1967, 1969). However, the fate of pyrazon in a food chain is not known. Recently, Metcalf *et al.* (1971) developed a model ecosystem to facilitate the study of the biodegradability and accumulation of pesticides in the environment. Several pesticides have been examined in this system (Yu *et al.*, 1974; Sanborn and Yu, 1973; Booth *et al.*, 1973). This study, which is part of a continuous effort to examine the fate and effects of pesti-

cides in the environment, considers the fate of pyrazon in a model ecosystem.



## MATERIALS AND METHODS

**Labeled Compound.** Pyridazinone ring-<sup>14</sup>C-labeled pyrazon (sp act., 4.7 mCi/mmol; radiochemical purity 98% by tlc and radioautography) was obtained from BASF Corporation.

**Model Ecosystem.** The procedures described by Metcalf *et al.* (1971) with some modifications (Yu *et al.*, 1974) were followed and the experiment with pyrazon was replicated two times simultaneously. Ring-<sup>14</sup>C-labeled pyrazon (2.36 mg, 50  $\mu$ Ci) in 0.5 ml of acetone was applied to the base of the 7-day-old sorghum plants.

**Sample Preparation.** The work-up procedures were described previously (Yu *et al.*, 1974).

Illinois Natural History Survey and Illinois Agricultural Experiment Station, Urbana, Illinois 61801.

<sup>1</sup> Present address: Department of Entomology, New York State Agricultural Experiment Station, Geneva, N.Y. 14456.

<sup>2</sup> Present address: Department of Zoology, Brigham Young University, Provo, Utah 84601.

<sup>3</sup> Present address: Agricultural Division, Monsanto Co., St. Louis, Mo. 63166.

<sup>4</sup> Present address: Department of Entomology, University of Illinois, Urbana, Ill. 61801.



NOTE TO FILE: 75318-A (B2E-01) (31 August 2005)

GAIL TOMIMATSU *G. Tomimatsu*

Intended Use Sites (Draft Label of Pinpunched 09 September 2004): tobacco processing & storage facilities, mushroom culture, stored products/warehouses; floodwaters, wastewater treatments, *other aquatic sites*

Regulatory Correspondence—Summary and Brief History to Date:

- Original Application Date: 18 Mar 2004 (pinpunched)
- One study failed 86-5 and was rejected
- DERs completed for Product Chemistry (27 Sep 2004) and Efficacy (30 Sep 2004)
- Submission: Revised Labels increasing use sites and rates; not supported by previous data nor studies
- 11 page Letter of deficiency for 6 products including 75318-A: 15 Dec 2004
- Revision of PRIA date from 29 Dec 2004 to 28 Mar 2005 **CONDITIONAL** upon receiving responses to identified deficiencies no later than 24 Jan 2005. Recommendation for JA to **RENEGOTIATION #1** (14 Dec 2005)
- B2E Biotech LLC responses submitted 14 Jan 2005
- BPPD Review of 14 Jan 2005 submission: 17 Feb 2005 & 10 Mar 2005: Product Chemistry → ACCEPTABLE; Efficacy → UNACCEPTABLE
- **2<sup>nd</sup> RENEGOTIATION**: from 28 Mar 2005 to June 28, 2005 (17 Mar 2005)
- Letter of Deficiencies; Review of Studies/Waivers for B2E response of Jan 14, 2005; 28 Mar 2005; Further Explanation of Why and What must be submitted to support intended uses and product registration;
- BPPD response of April 28 to address concerns and questions regarding B2E-06 (impacts B2E-01 product registration, also) of electronic letter from consultant, Amy Roberts (Mar 28, 2005); suggested data matrix included
- **3<sup>rd</sup> RENEGOTIATION**: from 28 Jun 2005 to 31 Oct 2005 **CONDITIONAL** upon receipt of materials for review by 15 July 2005. Nothing received as of 31 Aug 2005.

Throughout the review period, since March 2004, BPPD has been in contact with the registrant and the consultant, addressing questions and concerns in face-to-face meetings, electronic and telephone conversations. The staff have met all deadlines, (for administrative and science review) without "a good faith effort" from the registrant that required data will be forthcoming to address the deficiencies as outlined and recommended. The registrant has verbally "assured" that studies are underway (i.e., Tier II mysid shrimp), or will be done during September (prime mosquito month). Furthermore, the staff have reviewed protocols for studies (chronic mysid shrimp, determination of EEC and efficacy studies) within this PRIA timeframe (April 2004 thru July 2005) review period. The amount of time and resource expenditure (by the staff and Division management) has been extraordinary for this registrant. The registrant has been informed repeatedly that they can remove the aquatic uses on this label, and come back with applicable label amendments after BPPD review of the required studies and outstanding data. Yet, they still choose to re-negotiate PRIA due dates and "keep us hanging".



I recommend that the B2E Biotech LLC consider withdrawing this registration, given the outstanding data and studies required to support certain aquatic use sites/patterns, which remain compensable until about August 2006. Incidentally, they withdrew 75318-U and -E (per Agency letters dated June 13, 2005) because of outstanding data deficiencies. Alternatively, Bob T. suggested that B2E also has the option to change their submission to a non-PRIA action (which I understand, we are not obligated to adhere/respond to any time schedule); to keep the status for this product as "pending". In any case, we should issue a "cannot grant the registration" letter, on the basis that they did not meet the conditions as specified in the letter of 27 June 2005. Although the letter will reflect another option to re-negotiate the PRIA date, I believe that this option will only help the registrant further delay the studies; nevertheless I think we should place very strict conditions upon this 4<sup>th</sup> re-negotiation: e.g., we receive in writing, that certain studies are underway, or that study reports will be submitted by xx-xx-2005; so that we can have an idea of adjusting the timeframes for review.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Amy Plato Roberts  
for B2E Biotech, LLC  
Technology Sciences Group, Inc.  
1101 17<sup>th</sup> Street, NW, Suite 500  
Washington, DC 20036

JUN 27 2005  
779777 / 350  
MD / 38

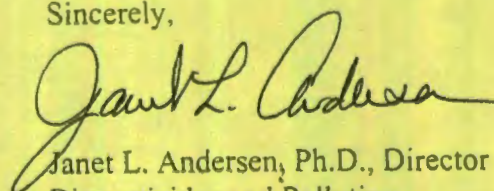
RE: Renegotiation of Decision Time Review  
Product Name: B2E-01  
EPA File Symbol: 75318-A

Dear Ms. Roberts:

The purpose of this letter is to confirm the agreement between the Agency and the company for which you act on behalf of (B2E Biotech, LLC), to extend the decision time review period for the above-referenced action with PRIA category code B67. In your May 31, 2005 offer to renegotiate, you requested to extend the time period ending June 28, 2005 for this action for an additional 120 days. As a result, the second renegotiated PRIA decision time period ending June 28, 2005 has now been extended until October 31, 2005, provided the Agency is in receipt of the anticipated submission by July 15, 2005.

If you have any questions, please contact Mari Duggard, (703-308-0028, [duggard.mari@epa.gov](mailto:duggard.mari@epa.gov)).

Sincerely,

  
Janet L. Andersen, Ph.D., Director  
Biopesticides and Pollution  
Prevention Division (7511C)

CONCURRENCES							
SYMBOL	7511C						
SURNAME	Duggard						
DATE	23 Jun 05						





**WASHINGTON**

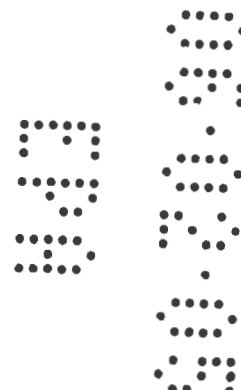
1101 17th Street, N.W.  
Suite 500  
Washington, D.C. 20036  
Telephone 202 223-4392  
Fax 202 872-0745

Janet Andersen  
Biopesticides and Pollution Prevention Division (7511C)  
Office of Pesticide Programs, EPA  
1801 South Bell Street  
Arlington, VA 22202

May 31, 2004

**RE: B2E-01; File Symbol 75318-A**

**Offer to renegotiate the PRIA due date**



Dear Dr. Andersen:

**SAN FRANCISCO**

Spear Tower, Suite 3622  
One Market  
San Francisco, CA 94105  
Telephone 415 293-8061  
Fax 415 293-8001

On behalf of B2E Biotech LLC, the purpose of this letter is to offer to renegotiate the PRIA due date for the above referenced pending application. At present, the PRIA due date for this application is June 28, 2005. The registrant is currently in process of generating data in response to a deficiency letter from the Agency (dated March 28, 2005), and expects to have a resubmission in by the end of June 2005. To allow the Agency sufficient time to review our resubmission, with this letter we hereby offer to renegotiate the due date to October 31, 2005.

Please respond back in writing (via email or letter) your agreement with this extension. We will advise the Agency promptly if there is any change in our anticipated resubmission date. Thank you in advance for your assistance and consideration on this matter.

**SACRAMENTO**

712 Fifth Street  
Suite A  
Davis, CA 95616  
Telephone 530 757-1298  
Fax 530 757-1299

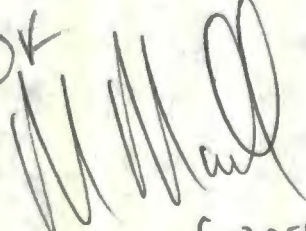
Sincerely,

Amy Plato Roberts  
Regulatory Consultant for B2E Biotech LLC  
Direct dial (202) 828-8964; email: [aroberts@tsgusa.com](mailto:aroberts@tsgusa.com)

cc: Bill Mintz, President, B2E Biotech LLC  
Mari Duggard, RAL, Biochemical Pesticides Branch, BPPD, EPA  
Linda Hollis, Team Leader, Biochemical Pesticides Branch, BPPD, EPA  
Sheryl Reilly, Chief, Biochemical Pesticides Branch, BPPD, EPA



Recommendation to Division Directors On Negotiated Due Dates and Denials			
Reg#: 75318-A	Action: B67	PRIA Mandated Time frame: 6 mos.	
Submitted by: Mari Duggard		Branch: BPB	Date: 13 Jun 05
Company: B2E Biotech, LLC			
Current Due Date: 28 June 2005			
<p><b>Issue (describe in detail):</b> The registration application is for an Insect Growth Regulator containing 33.6% (S)-Methoprene, to be formulated into pellets for use in tobacco processing and storage facilities. Toxicity and non-target organism data requirements per 40 CFR 158.690 have not been adequately satisfied via the registrant's submitted public literature and waiver rationale. The product performance data (required for control of public health pests) is currently unacceptable, but upgradable to acceptable pending submission and review of requested data and information. According to transmittal letter requesting to renegotiate the current decision date, the registrant is currently generating the necessary data to satisfy the guideline requirements for many of the company's pending registration products.</p>			
<p><b>Recommendation (include proposed new due date for renegotiations):</b> The registrant must address the unsatisfied toxicity issues within their next data submission. Additionally, the registrant's product performance data requires clarification regarding application techniques, labeled rates and estimation of efficacy, within 4 months: <u>October 31, 2005</u> given receipt of submission by 15 Jul 2005.</p>			
<p><b>Rationale:</b> This proposed PRIA renegotiation date will allow time for the registrant to submit the required materials, as well as time for Agency review and response to the submission. Also the materials to be submitted may potentially support the registration of other pending products - review of this material may help to expedite processing of other B2E Biotech, LLC registration applications.</p>			
<b>History</b>			
Original Due Date: 29 Dec 2004			
Has due date been renegotiated before: /X/ YES    /___/ NO			
If Yes Provide Complete History: See previous Renegotiation forms (attached)			

OK  
  
 6-20-05

**Describe Interactions With Company (describe in detail):**

The registrant was notified of major deficiencies in the submission through 15 Dec 04 deficiency letter, e-messaging communications throughout the review process, and off-agenda conversations with the registrant at a Pre-registration meeting. The registrant also received a more detailed, product-specific deficiency letter with last renegotiation (dated 28 Mar 05).



Recommendation to Division Directors On Negotiated Due Dates and Denials			
Reg#: 75318-A	Action: B67	PRIA Mandated Time frame: 6 mos.	
Submitted by: Mari Duggard		Branch: BPB	Date: 21 Dec 04
Company: B2E Biotech, LLC			
Current Due Date: 29 Dec 2004			
<b>Issue (describe in detail):</b> The registration application is for an Insect Growth Regulator containing 33.6% (S)-Methoprene, to be formulated into pellets for use in tobacco processing and storage facilities. Toxicity and non-target organism data requirements per 40 CFR 158.690 have not been satisfied, and are required to support registration of this product as it differs in inert composition from its proposed registered source (74032-1).			
<b>Recommendation (include proposed new due date for renegotiations):</b> Per 21 Dec 04 telephone conversation with registrant, a proposed new date of 28 Mar 05 has been suggested and mutually agreed to by both BPPD and registrant.			
<b>Rationale:</b> This proposed PRIA renegotiation date will allow time for the registrant to submit the required materials, as well as time for Agency review and response to the submission.			
<b>History</b>			
Original Due Date: 29 Dec 2004			
Has due date been renegotiated before: <input type="checkbox"/> / YES <input checked="" type="checkbox"/> / NO			
If Yes Provide Complete History:			
<b>Describe Interactions With Company (describe in detail):</b> The registrant was notified of major deficiencies in the submission through 15 Dec 04 deficiency letter, e-messaging communications throughout the review process, and off-agenda conversations with the registrant at a Pre-registration meeting.			
Other Comments:			



Recommendation to Division Directors On Negotiated Due Dates and Denials			
Reg#: 75318-A	Action: B67	PRIA Mandated Time frame: 6 mos.	
Submitted by: Mari Duggard		Branch: BPB	Date: 17 Mar 05
Company: B2E Biotech, LLC			
Current Due Date: 28 March 2005			
<p><b>Issue (describe in detail):</b> The registration application is for an Insect Growth Regulator containing 33.6% (S)-Methoprene, to be formulated into pellets for use in tobacco processing and storage facilities. Toxicity and non-target organism data requirements per 40 CFR 158.690 have not been adequately satisfied via the registrant's submitted public literature and waiver rationale. The product performance data (required for control of public health pests) is currently unacceptable, but upgradable to acceptable pending submission and review of requested data and information.</p>			
<p><b>Recommendation (include proposed new due date for renegotiations):</b> The registrant must address the unsatisfied toxicity issues, either through submission of data or revised waiver request rationale. Additionally, the registrant's product performance data requires clarification regarding application techniques, labeled rates and estimation of efficacy, within 3 months: June 28, 2005.</p>			
<p><b>Rationale:</b> This proposed PRIA renegotiation date will allow time for the registrant to submit the required materials, as well as time for Agency review and response to the submission.</p>			
<b>History</b>			
Original Due Date: 29 Dec 2004			
Has due date been renegotiated before: /X/ YES    /__ / NO			
If Yes Provide Complete History: See previous Renegotiation form (attached)			
<p><b>Describe Interactions With Company (describe in detail):</b> The registrant was notified of major deficiencies in the submission through 15 Dec 04 deficiency letter, e-messaging communications throughout the review process, and off-agenda conversations with the registrant at a Pre-registration meeting.</p>			





Amy Roberts  
<ARoberts@tsgusa.com>

05/31/05 10:06 AM

To Janet Andersen/DC/USEPA/US@EPA

cc Mari Duggard/DC/USEPA/US@EPA, Linda  
Hollis/DC/USEPA/US@EPA

bcc

Subject RE: B2E-01 (75318-A)

Agreed. I will send a formal letter today requesting a renegotiated out due date of 4 months (to October 31). Thanks in advance and best regards,

Amy Plato Roberts  
Technology Sciences Group Inc.  
1101 17th Street, NW, Suite 500  
Washington, DC 20036  
Direct dial: (202) 828-8964; Fax: (202) 872-0745  
www.tsghusa.com

-----Original Message-----

From: Andersen.Janet@epamail.epa.gov  
[mailto:Andersen.Janet@epamail.epa.gov]  
Sent: Tuesday, May 31, 2005 7:27 AM  
To: Amy Roberts  
Cc: Duggard.Mari@epamail.epa.gov; Hollis.Linda@epamail.epa.gov  
Subject: Fw: B2E-01 (75318-A)

Amy we have developed a standard way to divide the various parts of the work into Phases. A B67 is a 6 month action and this will require data to be screened for 86-5 as well as our screen and to undergo review. However, we have done some work on this product so parts of the process will be faster. Assuming the package actually does come in at the end of June, then I would suggest 4 additional months rather than 3.

----- Forwarded by Janet Andersen/DC/USEPA/US on 05/31/2005 07:18 AM -----

Mari  
Duggard/DC/USEPA  
/US

05/27/2005 04:07  
PM

To  
Janet Andersen/DC/USEPA/US@EPA  
cc  
Subject  
Fw: B2E-01 (75318-A)

Janet,

This would be the third re-negotiation for this product - but it is because they'll be coming in with "real data" in efforts to support the unacceptable sites and other products.

----- Forwarded by Mari Duggard/DC/USEPA/US on 05/27/05 04:02 PM -----

Amy Roberts  
<ARoberts@tsghusa.com>

05/27/05 03:43  
PM

To  
Mari Duggard/DC/USEPA/US@EPA  
cc  
Linda Hollis/DC/USEPA/US@EPA  
Subject



RE: B2E-01 (75318-A)

Dear Mari -

Thanks for your message, I was actually just thinking of this myself this morning!

We plan on submitting a response to the EPA deficiency letter along with some new data to support registration. The new data is in the works right now and at this time the anticipated submission date for the response + new data is the end of June. As such, I would like to RENEGOTIATE out the PRIA due date to allow for enough time for BPPD to review the information. I would like to suggest September 30 as the renegotiated PRIA due date. Please advise whether or not that would be acceptable, and I will formalize the renegotiation request in writing.

Best regards and have a great holiday weekend,

Amy Plato Roberts  
Technology Sciences Group Inc.  
1101 17th Street, NW, Suite 500  
Washington, DC 20036  
Direct dial: (202) 828-8964; Fax: (202) 872-0745 [www.tsgusa.com](http://www.tsgusa.com)

-----Original Message-----

From: Duggard.Mari@epamail.epa.gov [mailto:Duggard.Mari@epamail.epa.gov]

Sent: Friday, May 27, 2005 2:32 PM

To: Amy Roberts

Cc: Hollis.Linda@epamail.epa.gov

Subject: RE: B2E-01 (75318-A)

Hi Amy,

Regarding the status of the resubmission for B2E-01(75318-A) - is B2E Biotech ready (or close to being ready) to submit the necessary information per the 28 Mar 05 deficiency letter? The re-negotiated due date was set for 28 Jun 05, however the confirmation of renegotiated date letter (also dated 28 Mar 05) inadvertently left out a "received by date" so that BPPD can ensure enough time is allotted for review. Therefore, we really need to understand if the registrant will be submitting the material within a very small and upcoming time frame. Please reply to this message, or give me a call with your response.

Thanks,  
Mari D.  
703-308-0028





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,  
PESTICIDES AND TOXIC  
SUBSTANCES

April 28, 2005

Ms. Amy Plato Roberts  
Regulatory Consultant for  
Mr. William Mintz  
B2E Biotech LLC Corporation  
Technology Sciences Group, Inc.  
1101 17<sup>th</sup> St., NW, Suite 500  
Washington, DC 20036

RE: BPPD response to Further Questions on B2E-06 science review electronically  
transmission send to BPPD Staff on March 23, 2005

Dear Ms. Roberts,

The BPB staff of BPPD and the Office of General Counsel has reviewed your questions and concerns regarding the science review of B2E-06 (EPA Reg No. 75318-5) and provide the following responses and clarifications to your letter, sent electronically on March 23, 2005. Your original text and questions are followed by our responses.

**Questions on the B2E-06 science review:**

- 1) It is not as if all of the data submitted is unacceptable. We submitted:
  - a. Data waiver rationale for OPPTS 850.1350 (Mysid Chronic Toxicity Test) [MRID 46445501]
  - b. Data waiver rationale for OPPTS 850.1400 (Fish Early Life-Stage Toxicity Test) [MRID 46445501]
  - c. Ecological risk assessment for S-Methoprene [MRID 46445502]

It would appear from the science review that the data waiver rationale for the mysid study and the eco risk assessment were not acceptable, but that the data waiver rationale for the fish early-life stage is. Can EPA clarify which of the above three are rated ACCEPTABLE and UNACCEPTABLE?



BPPD response: The BPPD review stated that MRIDs 46445501 and 46445502 (Items a, b, and c, above) were ACCEPTABLE, "no further data are required" (February 17, 2005 memorandum from A. Gonzales to M. Duggard). To clarify, ACCEPTABLE classification means a study or waiver rationale is scientifically acceptable (i.e., the data generated are credible and the study is conducted in an acceptable manner) and can be used in support of a regulatory decision. It does not mean that no toxicity or adverse effects were identified in the study. B2E submitted published studies as a rationale for waivers of the required studies Guideline 850.1350 (Chronic Mysid Shrimp Toxicity Test) and Guideline 850.1400 (Fish Early Life-Stage Toxicity Test). While these were scientifically acceptable based on the definition above, BPPD's review of those studies identified adverse effects (reproductive) that did not support the use of the B2E products in estuarine and marine use sites. Therefore, our regulatory decision was to not allow these use sites on the label at this time.

2) The science review states "the submitted data do not support estuarine and marine use sites on the label." The science review does not specify, however, what data is required to support estuarine and marine use sites. BPPD stated in emails (from Gail Tomimatsu dated 8/5/04 and from Linda Hollis dated 2/24/05) that the science reviews would provide details on the "necessary information required to support registration of the remaining pending products and for specific use sites." What data is necessary to support the estuarine and marine use sites on the original labels?

BPPD response: Fresh water, salt water and estuarine marine waters are aquatic use sites that must be supported by certain data in order to be approved as use sites for biochemical pesticides. Based on the regulatory history of the subject active ingredient, the Agency has required a certain guideline study be submitted in support of these uses sites [Chronic Mysid Shrimp Study (a Tier III study)], and this data requirement was communicated to B2E. To satisfy this data requirement, B2E submitted: (1) literature from a Chronic Mysid Shrimp Study as conducted by EPA Laboratories, and (2) a "risk assesment" which interpreted the cited study. Upon Agency review of the submittted information, it was determined that there exists a potential for adverse effects to the surrogate test organism, which could raise concerns about those effects to other non-target organisms as well. Thus, the above use aquatic use sites were not allowed at this time.

To understand how the Agency makes such determinations it should be stated that FIFRA requires EPA to evaluate a pesticide's potential adverse effects to human health and the environment (FIFRA Section 3(c)(1)(F)). Based on the information available, we must make a determination that use of the pesticide will not cause unreasonable adverse effects when the risks and benefits are considered. Pesticide risk assessments result from scientific reviews of numerous product/residue chemistry, mammalian toxicity and ecotoxicity studies (40 CFR Part 158). Adverse effects to the environment (and its inhabitants) include risks "measured" as a function of hazard (toxicity) and exposures. Single-species toxicity tests measure a number of biological endpoints of non-target organisms in a wide variety of fauna and flora taxa (40 CFR §§158.490, 158.590, and 158.690(d)). Both the mysid shrimp and the fathead minnow are scientifically valid preferred test organisms for assessing potential hazards to estuarine/marine inhabitants; they are easily reared in the laboratory and are commonly used for hazard testing of



toxic substances, including conventional chemical pesticides. For the single-species, non-target organism testing, the common endpoint is mortality; however, other endpoints are useful to evaluate a pesticide's safety (such as growth effects on immature stages, or reproductive effects). Other effects (e.g., non-target organism population declines; loss of habitat or food source, community-level effects) may trigger additional higher Tier toxicity testing of the biochemical [40 CFR 158.690(d), Tier II], or field dissipation studies [40 CFR 158.690(d)] on a case-by-case basis. The potential for adverse effects to the test organism, mysid shrimp were documented in the risk assessment (MRID 46645502) submitted by B2E. This calculated environmental effects concentration or EEC (2.2 ug/L) exceeds the threshold at which adverse reproductive effects occurred in the mysid shrimp study. As a result, the estuarine and marine aquatic use patterns were not allowed at least at this time. BPPD has been conducting a more thorough risk assessment on the aquatic uses of methoprene; and will need to consider listed threatened or endangered species (Endangered Species Act, Section 7). Also we must weigh the benefits versus the risk(s) before completing our evaluation of methoprene uses in accordance with FIFRA.

The PRIA time frame did not allow for this kind of extensive additional work, but BPPD did find a mechanism to give B2E some potential to sell their product until the remaining issues can be fully addressed. Potentially there are additional studies that could be conducted such as testing other appropriate aquatic invertebrates and providing an assessment that can be used to evaluate potential impacts on any listed threatened or endangered species. It may be that higher tiered studies will help resolve the issues. B2E would have to conduct guideline studies or credible technical literature to show that the observation of reproductive toxicity in the submitted study was an anomaly, or unlikely to cause unreasonable adverse effects. The argument that the use of the "rapid dissipation" of the methoprene molecule from a "slow-release" product, such as a briquet that is intended to last for weeks or months is inadequate to support a case that exposure would not occur during the reproductive phase of aquatic insects without supportive data. Before such data are generated, BPPD would like to complete its risk assessment, but if B2E intends to proceed with further testing, the company representatives should discuss which tests are going to be conducted and we recommend all protocols gain BPPD approval before the testing is conducted.

3) Further, EPA had us remove "rice fields" and "areas that drain into public waterways," but there is no information in the science review as to why the data submitted does not support these uses, and what data is required to support these uses. What data is necessary to support these uses?

*BPPD response:* Mysid shrimp was tested as a surrogate species for aquatic invertebrates. Rice fields and areas that drain into public waterways which would be treated with this product could exceed the calculated EEC adverse effects level. Aquatic invertebrates are found in flooded rice fields and in public waterways. Areas that would be treated with B2E's products that are slow release such as briquets, might release methoprene or parts of the end-use product which can enter the stream, pond, or lake before the methoprene is degraded or dissipated. Data to show that the threshold for adverse effects levels would not be exceeded under field conditions would be the type of information useful in consideration of removing these use site restrictions.



Additionally, according to Agency files, the submitted data to support uses on rice fields are still compensable.

4) The science review states "the registrant was to address the inerts in the MP and their possible cumulative negative effects with (S)-Methoprene." Our understanding of the OPPTS guideline for the mysid chronic study is that typically the test substance is the technical grade active ingredient, not the formulated MP or EP. Why would the inerts in the MP need to be addressed in terms of cumulative negative effects? Is that part of the data requirement? We would like to point out that in our case, the MP inerts are all List 4 or GRAS.

BPPD response: The inerts question addresses the issues of enhanced toxicity of methoprene. Synergism with methoprene may enhance adverse effects on non-target organisms. Since we know technical methoprene has adverse effects on non-target organisms, BPPD suggested in our previous correspondence that B2E address whether the inerts in the end-use products might enhance toxicity (or exposures) of methoprene to non-target organisms. This is not a deficiency and was not identified as a deficiency in these correspondences.

#### Clarification of the data requirements:

5) Attached is our draft of a template data matrix for an end-use product containing methoprene, which lists the data requirements as we understand them. The data requirements are the standard Tier 1 biochemical pesticide requirements PLUS two Tier II ecotoxicity data requirements as noted in the Methoprene RED. Will EPA please confirm that the attached template data matrix is accurate, or will EPA please correct as needed?

#### BPPD Response:

BPPD is providing a "suggested" data matrix; however this data matrix is subject to revision pending actual submission of an application for pesticide registration, and/or upon formal meetings and discussions with BPPD personnel. In addition, a list of potential studies to support an end use product is provided below. Citations of studies (i.e., MRID), waiver requests for a respective guideline are normally reviewed in the context of that particular application. Generally, for any biochemical end-use product with public health pest control claims (e.g., mosquitoes), the following data requirements must be on the data matrix and supported by a study, or waiver request, accompanied with scientific rationale: All product analysis data requirements (40 CFR § 158.690), all tier I biochemical toxicology data requirements (40 CFR § 158.690(c)), all tier I non target organism data requirements (40 CFR § 158.690(d)), and efficacy testing (OPPTS 810.3400).

For a biochemical with an active ingredient such as methoprene, with aquatic uses, BPPD recommends that B2E consider additional testing, such as Tier II studies on aerobic aquatic biodegradation (OPPTS 835.3100), biodegradability in seawater (OPPTS 835.3160), direct photolysis rate in water by sunlight (OPPTS 835.2210), and hydrolysis as a function of pH and temperature (OPPTS 835.2130), and additional non-target aquatic invertebrate (insect) toxicity studies. Aquatic invertebrate studies (OPPTS 850.1950) could be used to develop an ecological risk assessment; followed by an analysis of potential impacts on listed threatened or endangered species.

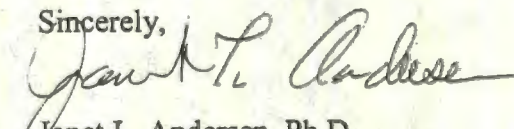


6) There has been confusion on our side as to what the data requirements are, beyond Tier I, and when are they triggered. Our understanding is that EPA is now requiring the Tier II ecotox data for any product applied to an estuarine and marine use site, rather than just to slow release (>30-day) products as is specified in the RED. The RED is quite clear that mysid and fish early-life cycle data was required only to support slow release briquets, not to support other (short release) formulations of methoprene applied in estuarine and marine environments. Will EPA please confirm WHEN tier II ecotox data requirements are triggered

*BPPD Response:* Tier I testing for biochemical pesticides requires fresh water invertebrate testing when the product is to be directly applied to aquatic environments. Adverse effects (toxicity and potential exposures) in Tier I (acute) non-target organism studies may trigger additional studies. These may be guideline or non-guideline studies which is determined on a case by case basis. Higher Tier (II and III) tests are triggered when the results of Tier I test(s) show adverse effects to non-target organisms at or above levels likely to be found in the environment. Because the proposed use sites included estuarine and marine sites, mysid shrimp were an appropriate indicator species. Note that Tier II and III studies for biochemical pesticides address fate and effects of the pesticide, not direct toxicity to non-target organisms.

We hope that the above text and explanations help you understand the complexities in defining data requirements for assessing a pesticide's environmental safety; and help you in addressing specific questions relative to B2E-06 (EPA Reg. No. 75318-5; formerly 75318-L).

Sincerely,



Janet L. Andersen, Ph.D.,  
Director  
Biopesticides and Pollution  
Prevention Division (7511C)

Enclosure:

A Suggested Data Matrix for methoprene end-use product



# Suggested Data Matrix; SUBJECT TO REVISION

Form Approved OMB No. 2070-0060

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The Public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPP Information Management Division (2137) U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

### DATA MATRIX

Date	EPA Reg. No./File Symbol	Page 1 of 45
Applicant's/Registrant Name and Address		Product (Template data matrix for a methoprene end-use product)

**Ingredient** (S)-Methoprene (CAS No. 65733-16-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 880.1550	Product Identity and Composition				
OPPTS 880.1600	Description of products used to produce the formulation				
OPPTS 880.1620	Description of the Formulation Process				
OPPTS 830.1750	Certified Limits				
OPPTS 830.1800	Enforcement Analytical Method				
OPPTS 830.6302	Color				
OPPTS 830.6303	Physical State				
OPPTS 830.6304	Odor				
OPPTS 830.6313	Stability at Normal and Elevated Temperatures, Metals and Metal Ions				
OPPTS 830.6314	Oxidation/Reduction				
Signature			Name and Title		Date



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**401 M Street, S.W. WASHINGTON, D.C. 20460**

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**DATA MATRIX**

<b>Date</b>	<b>EPA Reg. No./File Symbol</b>	<b>Page 2 of 4/5</b>
<b>Applicant's/Registrant Name and Address</b>		<b>Product</b> <b>(Template data matrix for a methoprene end-use product)</b>

**Ingredient** (S)-Methoprene (CAS No. 65733-16-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.6315	Flammability				
OPPTS 830.6316	Explosibility				
OPPTS 830.6317	Storage Stability				
OPPTS 830.6319	Miscibility				
OPPTS 830.8320	Corrosion Characteristics				
OPPTS 830.6321	Dielectric breakdown voltage				
OPPTS 830.7000	pH				
OPPTS 830.7050	UV/visible absorption				
OPPTS 830.7100	Viscosity				
OPPTS 830.7200	Melting Point				
OPPTS 830.7220	Boiling Point				
OPPTS 830.7300	Bulk Density				
OPPTS 830.7370	Dissociation Constant				
OPPTS 830.7550	Partition Coefficient				
<b>Signature</b>			<b>Name and Title</b>	<b>Date</b>	



Suggested Data Matrix; Subject to Revision.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W. WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date	EPA Reg. No./File Symbol	Page 3 of 45
Applicant's/Registrant Name and Address		Product (Template data matrix for a methoprene end-use product)

Ingredient (S)-Methoprene (CAS No. 65733-16-8)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.7840	Water Solubility				
OPPTS 830.7950	Vapor Pressure				
OPPTS 870.1100	Acute Oral Toxicity - Rat				
OPPTS 870.1200	Acute Dermal Toxicity - Rabbit				
OPPTS 870.1300	Acute Inhalation Toxicity - Rat				
OPPTS 870.2400	Primary Eye Irritation - Rabbit				
OPPTS 870.2500	Primary Dermal Irritation - Rabbit				
OPPTS 870.2600	Dermal Sensitization - Guinea Pig				
OPPTS 870.3100	90-Day Oral Toxicity - Rat				
OPPTS 870.3250	90-Day Dermal Toxicity				
OPPTS 870.3465	90-Day Inhalation Toxicity				
OPPTS 870.3700	Teratogenicity				
OPPTS 870.5000	Genotoxicity				

Signature	Name and Title	Date
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"Suggested Data Matrix ; Subject 12 Keweenaw

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W. WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date		EPA Reg. No./File Symbol		Page 4 of 45	
Applicant's/Registrant Name and Address		Product (Template data matrix for a methoprene end-use product)			
Ingredient (S)-Methoprene (CAS No. 65733-16-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 880.3550	Immunotoxicity				
OPPTS 850.2100	Avian Acute Oral Toxicity				
OPPTS 850.2200	Avian Dietary Toxicity				
OPPTS 850.1075	Fish Acute Toxicity - Freshwater and Marine				
OPPTS 850.1010	Aquatic Invertebrate Acute Toxicity				
OPPTS 850.4100	Non-target Plant Studies				
OPPTS 880.4350	Non-target Insect Studies				
OPPTS 850.1350 (Tier II)	<i>Shrimp</i> Mysid Chronic Toxicity Test				Per Methoprene RED, required only for saltwater & estuarine uses of slow release (>30-day) products
OPPTS 850.1400 (Tier II)	Fish Early Life-Stage Toxicity Test				Per Methoprene RED, required only for saltwater & estuarine uses of slow release (>30-day) products
OPPTS 810 Series	Product Performance Data				
Signature			Name and Title		Date



# Suggested Data Matrix, Subject to Revision



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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## DATA MATRIX

Date		EPA Reg No./File Symbol		Page 1 of 1	
Applicant's/Registrant's Name & Address		Product			
Ingredient					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 835.3100	Aerobic aquatic biodegradation				
OPPTS 835.3160	Biodegradability in seawater				
OPPTS 835.2210	Direct Photolysis rate in water by sunlight				
OPPTS 835.2130	Hydrolysis As A Function Of PH and Temperature				
OPPTS 850.1950	Field Testing for Aquatic Organisms				
Signature			Name and Title		Date



[illegible]



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

William K. Mintz  
B2E Biotech, LLC  
500 Mamaroneck Ave., Suite 201  
Harrison, NY 10528

MAR 28 2005

773047 / B67  
MD / 13

RE: Your re-submission to Agency deficiency letter dated 15 Dec 2004  
B2E-01 (EPA File Symbol 75318-A; an end-use product for use in tobacco processing, storage facilities and waste water treatment facilities)

Dear Mr. Mintz:

The application referred to above, submitted in connection with registration under FIFRA section 3(c)(5) has been reviewed by BPPD and deficiencies have been identified and are as follows.

Confidential Statement of Formula (CSF) Revision

In box 10 on the CSF, for the ingredient [REDACTED] it must be listed with the other components, along with its percentage in the composition and CAS number.

Toxicology

MRID 46445801 (Response to Tier I Biochemical Pesticide Data Requirements for B2E-01) contains requests to waive all acute toxicity data requirements and rationales to the request. The submitted rationales sufficiently addressed the acute oral toxicity data requirement, but did not adequately discuss the remaining guideline requirements. Your data waiver request has been granted for <sup>(1)</sup> the acute oral toxicity data requirement, based on the information discussed in the rationale (OPPTS Guideline 870.1100) and for <sup>(2)</sup> the acute dermal toxicity data requirement (OPPTS Guideline 870.1200), because dermal toxicity is not expected based on what is known about the inert ingredients. The following acute toxicology data requirements were not satisfied through review of your rationale and must be addressed through the submission of quantitative data or literature for each specific route of exposure, in addition to addressing possible human exposure scenarios for each route of exposure:

Acute inhalation (OPPTS Guideline 870.1300)  
Primary eye irritation (OPPTS Guideline 870.2400)  
Primary skin irritation (OPPTS Guideline 870.2500)  
Dermal sensitization (OPPTS Guideline 870.2600)

Product Performance Data

Your product label includes claims against public health pests (filter flies, midges, floodwater mosquitoes) for which efficacy data is required. The submitted product performance studies (MRIDs 42625405-07) have been classified as supplemental, but upgradeable pending characterization of application methods and rates used in the studies. The submitted product performance addendums (MRIDs 46453001 and 46453002) are insufficient to upgrade the efficacy data to acceptable. You must correct and/ or clarify the following deficiencies:

- a. Your product performance data tests the formulation for B2E-01 containing 33.6% S-Methoprene at certain label rates and proportionally estimates its effectiveness at higher dosage rates. Your addendum to the submitted data provides reasoning and explains the methodology of extrapolating and bridging up from usage rates, but it is not an acceptable demonstration of the product's efficacy. Product performance cannot be estimated by approximation, therefore

SYMBOL	B751C						
SURNAME	Duggard						
DATE	28 MAR 2005						

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deficiency 1  
3/28/12



you must provide exact percent IE according to labeled rates, or remove the directions for use and any references on the product label to rates that have not been tested.

- b. Your product performance data tests the formulation for B2E-01 containing 33.6% S-Methoprene using certain application techniques as listed on the proposed product label. Because your product claims control of a public health pest, all application techniques suggested by the product label must be tested and product performance studies must be conducted according to the Directions for Use as specified on the label. Your submitted data fails to examine efficacy of the test formulation for the aerial application method. Efficacy data and/ or acceptable rationale which address the potential hazards of aerial application is needed to support this application method, or it must be removed from the proposed product label.
- c. Your product performance data and proposed product label includes the terms "dense vegetation" and "deeper water." The definition of these terms may vary among applicators and must be quantitated.

#### Non-target Organism Data

Per your Data Matrix dated 1 Mar 2004, you intend to rely on data that was generated to support registration of S-Methoprene Technical R-ST SM IGR, your source technical product (EPA Reg. No. 74032-1; Hartz) to satisfy the non-target organism data requirements for this end-use Methoprene product. Upon Agency reexamination of the non-target data submitted for the Hartz Technical source, it was determined that the data are sufficient to support registration of the Technical product only and that these data could not be used in support of registration of any other S-Methoprene containing end-use product. Therefore, you must submit acceptable non-target organism data on the B2E-01 formulation or remove all natural aquatic use sites (freshwater marshes, salt water marshes, grassy swales, floodplains, etc.) and sites where runoff can occur into these use sites.

It was noted that within your transmittal letter accompanying the 14 Jan 2005 resubmission, the non-target organism data and risk assessment submitted in support of the registration application for B2E-06 (MUP 75318-5) was also intended by B2E Biotech, LLC to support the existing registration for S-Methoprene Technical R-ST SM IGR, the registered source of A.I. for this product, B2E-01. Data submitted to support registration applications or existing registrations, must be submitted in compliance with PR Notice 86-5 for each product or proposed product. Therefore, the data for B2E-06 (MUP) was not reviewed in light of 74032-1, rather a separate application and submission of materials must be made.

#### Data Matrix

Throughout the registration process, you have made changes to your registration application which are not accurately documented within your current Data Matrix (dated 1 Mar 04). You must submit an updated Data Matrix that reflects the current methods of addressing end-use product data requirements.

#### Product Label Review (refer to enclosed annotated label)

- a. Please indicate the net content/ weight of the product. (pg. 1)
- b. Based on the data submitted and the information discussed above regarding non-target data requirements, application of B2E-01 into estuarine and marine use sites may pose toxicity concerns to non-target organisms in these use sites. Please revise the Environmental Hazards statement to read:

*"Do not apply to water that drains into public waterways. For control of floodwater pests, use only in manmade sites as described on label." (pg. 2)*



- c. It is preferred by the Agency that the Storage & Disposal section of a product label be displayed in boxed format, so that it can be easily distinguished from other labeling language. (pg. 2)
- d. Please incorporate the phrase, "To the fullest extent permitted by law," to your warranty statement, as it currently contains overly broad language regarding the limitations of liability. (pg.2)
- e. Please revise the 3<sup>rd</sup> sentence in the Agricultural Use Requirements box to read:  
*"It contains requirements for training, decontamination, notification to workers, and emergency assistance."* (pg. 4)

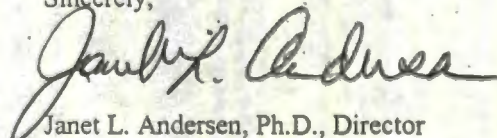
~~Under the Use Notes for Application as an aqueous spray, remove the final sentence:~~  
*"B2E-01 can also be used or mixed with diatomaceous earth."* (pg. 7)

- g. As mentioned above in the deficiencies cited for product performance, you must address the application methods and use rates not tested in your submitted data, or remove those application techniques and labeled rates from the proposed product label.
- h. Under the heading "Application Sites," revise the 1<sup>st</sup> sentence to read:  
"Apply B2E-01 as directed above to the following use sites which support mosquito larval development: woodland pools and meadows, pastures and rangelands, vineyards, fruit and nut orchards, berry fields and bogs\*, and other manmade depressions where mosquitoes may breed which do not runoff into any natural aquatic habitats.

\* Qualify the use site bogs by specifically identifying peat bogs. If peat bogs are not the intended use site, bogs must be deleted, so as not to confuse with cranberry bogs, etc.

Your application, as submitted under the Pesticide Registration Improvement Act (PRIA), has a decision date of **28 March 2005**. With the deficiencies listed above, we cannot approve your application. Please supply the missing guideline studies or data waiver requests with scientific rationales, correct the label and address all deficiencies as described above. If you cannot address these deficiencies immediately, please contact Mari Duggard (703-308-0028, [duggard.mari@epa.gov](mailto:duggard.mari@epa.gov)) or myself. We are willing to renegotiate your decision date, and may need to do so because the data and/or waivers will require more time to review than is remaining before the PRIA date. If you wish to negotiate your decision date, please contact me directly.

Sincerely,



Janet L. Andersen, Ph.D., Director  
Biopesticides and Pollution  
Prevention Division (7511C)

Enclosures: copy of draft label with comments



**B2E-01  
MASTER LABEL**

*Draft*

**An Insect Growth Regulator**

*(to control insect pests in tobacco processing and storage facilities)  
(to prevent emergence of adult Sciarid flies in mushroom culture)  
(to prevent the emergence of stored product insects)  
(to prevent the emergence of adult filter flies & non-biting midges)  
(to prevent the emergence of adult floodwater mosquitoes)*

**ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #85733-16-6)..... 33.6%  
OTHER INGREDIENTS:..... 66.4%  
Total:..... 100.0%

EPA Reg No. 75318-  
EPA Est. No.

B2E Biotech LLC  
500 Mamaroneck Avenue  
Harrison, NY 10528

*net weight:*

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**See (back panel) (side panel) (insert label) for additional precautionary statements**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**FIRST AID**

**If in eyes**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
- Call a poison control center or doctor for treatment advice.

**If on skin**

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

**If swallowed**

- Call a poison control center or doctor for treatment advice
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give any liquid to the person.
- Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-XXX-XXX-XXXX for emergency medical treatment information.



## ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of rinsate or equipment washwaters.

*apply to water that drains into public waterways*

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### PESTICIDE STORAGE

Store in a cool, dry place.

### PESTICIDE DISPOSAL

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. Do not reuse container.

## WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. ~~Buyer assumes~~ all risks of use and handling of this material when such use and handling are contrary to label instructions.

*To the fullest extent*

Always read the label before using this product.

For information, call 1-XXX-XXX-XXXX or visit our web site: [www. .com](http://www. .com)

## **(Directions for Use for B2E-01 to control insect pests in tobacco processing and storage facilities)**

## **FOR PROTECTION OF STORED TOBACCO FROM DAMAGE BY CIGARETTE BEETLE (*LASIODERMA SERRICORNE*) AND TOBACCO MOTH (*EPESTIA ELUTELLA*)**

### INTRODUCTION

B2E-01 is an emulsifiable concentrate formulation of the insect growth regulator, (S)-Methoprene. It is designed for use as a space spray in cold aerosol generators and in liquid concentrate form as an aqueous emulsified spray. Unlike traditional pesticides, (S)-Methoprene does not immediately kill immature insects; instead, it interferes with the normal insect development process and prevents adult pest emergence. B2E-01, prevents the adult emergence and reproduction of the Cigarette beetle (*Lasioderma serricorne*) and Tobacco moth (*Ephestia elutella*) when used according to label directions.

*spray -  
dermatol  
skin  
eyes - too?*

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment that will achieve uniform dispersal for best treatment results.

*remove tobacco?*

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for a minimum of 30 minutes (longer if possible) to allow the fine spray mist to settle. Do not remain in treated areas after treating. Ventilate treated areas before reentry. Repeat application as required.

### APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Repeat application as required.



#### MIXING INSTRUCTIONS

Partially fill clean application tank with water, add the specified amount of B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

***(Directions for Use for B2E-01 to prevent emergence of adult sciarid flies in mushroom culture)***

### AN INSECT GROWTH REGULATOR TO PREVENT THE EMERGENCE OF ADULT SCIARID FLIES IN MUSHROOM CULTURE

(WPS Language to be included in the Precautionary Statements)

#### Personal Protection Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. For more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber (≥14 mils), barrier laminate, or viton (≥14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### Engineering Control Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)]. The handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

#### User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### INTRODUCTION

S-Methoprene, the active ingredient in B2E-01 insect growth regulator (IGR), is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of S-Methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. B2E-01 prevents the emergence of adult Sciarid flies from the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adult flies present at the time of application will not be affected. If high adult fly populations are present, an initial use of a conventional adulticide will insure the best overall results. After treatment with B2E-01, larvae will continue to develop to the pupal stage where they will die. As B2E-01 prevents adult fly emergence, adult fly populations will be reduced over time. As maximum control is achieved two weeks after treatment, control assessment should be made at this time for most accurate evaluation.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.



to workers

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses on this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: if the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber, (≥14 mils), barrier laminated, or viton (≥14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.

#### METHOD, RATE, AND TIMING OF APPLICATION

Use either METHOD A, METHOD B, METHOD C, METHOD D or METHOD E

##### APPLICATION INSTRUCTIONS:

##### A. INCORPORATE AT TIME OF CASING

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft. Make spray application evenly, and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface immediately after placement.

##### B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING WHEN CASING LAYER IS PLACED ON COMPOST

###### In Compost:

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution. Spray on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

###### In Casing:

Mix B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

##### C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a spawn run longer than 15 days, a split application can be used.

###### First Application, On Compost:

Apply B2E-01 12 to 13 days after spawning. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

###### Second Application, In Casing:

Apply B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

##### D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS

###### First Application, In Casing:

Apply B2E-01 at the rate of 5½ fl. oz. per 1,000 sq. ft. in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

###### Second Application, On casing surface just prior to break:

Apply B2E-01 at the rate of 2¼ fl. oz. of per 1,000 sq. ft. in adequate water for even distribution as a surface drench prior to first break of mushrooms.



#### E. DELAYED CASING SURFACE DRENCH

##### Surface drench 7 days after casing:

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

##### Surface drench 7 days and 14 days after casing:

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### First Application on Casing:

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.

##### Second Application on Casing:

Apply B2E-01 14 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### MIXING AND HANDLING INSTRUCTIONS

Partially fill clean application tank with water, add the specified amount of B2E-01, mix, and complete filling with water. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

#### EFFECT ON MUSHROOMS

In most cases, treatment with B2E-01 has a beneficial effect on mushroom yield by reducing Sciarid fly larval damage. As mushroom production practices differ among growers, the user can conduct small plots treatments to verify that reduced crop yields will not occur under cultural conditions used.

#### *(Directions for Use for B2E-01 to prevent the emergence of stored product insects)*

#### **AN INSECT GROWTH REGULATOR TO CONTROL STORED PRODUCT INSECTS IN STORED FOOD COMMODITIES, SUCH AS CEREAL GRAINS, GRAIN SORGHUM (MILO), CORN, POPCORN, BIRDSEED, PEANUTS, SUNFLOWER SEEDS & TO CONTROL INSECT PESTS IN SEEDS**

#### INTRODUCTION

(S)-Methoprene, the active ingredient in B2E-01, protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, B2E-01 is not an adulticide, but its residual activity prevents the development of larvae from developing into adults. B2E-01, when used according to the label directions, prevents regeneration of these and other insect pests: Almond Moth (*Ephestia cautella*), Indian Meal Moth (*Plodia interpunctella*), Cigarette Beetle (*Lasioderma serricorne*), Lesser Grain Beetle (*Rhyzopertha dominica*), Sawtooth Grain Beetle (*Oryzaephilus surinamensis*), Merchant Grain Beetle (*Oryzaephilus mercator*), Red Flour Beetle (*Tribolium castaneum*), and Confused Flour Beetle (*Tribolium confusum*). Treat existing insect populations with an adulticide before applying B2E-01 for residual protection.

Apply B2E-01 to any food commodity (including but not limited to: cereal grains, corn, sunflower, canola, popcorn, wheat, spices, sorghum, rice, cocoa, peanuts, oats, and millet) for control of insect larvae. Use B2E-01 to treat pet food, animal feedstuffs, birdseed, and cotton hulls. B2E-01 can be applied to seed stock. Treated commodities can be processed within 24 hours following application.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

**Stored Commodities:** For protection of stored food, grains, animal feed, seeds used for oil and seed stock against stored product insects – for optimum results, thoroughly clean and treat storage areas prior to storing commodities. Apply B2E-01 to a top-dressing to stored products that have already been placed into bins or storage areas. For top-dressing applications, spray or fog the bin headspace paying particular attention to the top on the commodity mass, beams, ceilings, and rafters. Thorough coverage is essential. For surface treatments, apply 1 ml (1/30 oz.) of B2E-01 per 1000 square feet; or for space spray, apply 3 ml (1/10 oz.) per 10,000 cubic feet in sufficient water to provide adequate coverage. Do not flood top-dress area.



## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED:** Dilute B2E-01 with water and apply to the moving grain stream as a uniform coarse spray. Final water dilution volume is 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. Lower volumes of diluent can be used but, it is important to assure that the commodity mass is uniformly treated. Agitate water dilution during application.

A range of rates for different commodities is provided for flexibility during varying storage periods and conditions. For maximum residual, use higher rates; the lowest application rate offers shorter residual for commodities stored  $\leq 6$  months.

Apply B2E-01 in solution in accordance with the general directions, to stored products at the following rates per 1,000 bushels:

	fl oz	ml	fl oz	ml	fl oz	ml
Wheat	14.0	420	7.0	210	1.75	52
Corn	14.0	420	7.0	210	1.75	52
Sorghum (Milo)	14.0	420	7.0	210	1.75	52
Barley	12.0	360	6.0	180	1.50	45
Rice	12.0	360	6.0	180	1.50	45
Oats	8.0	240	4.0	120	1.0	30
Peanuts	8.0	240	4.0	120	1.0	30
Sunflowers	8.0	240	4.0	120	1.0	30

For information on rates for other commodities, contact your distributor.

## USE NOTES:

- Apply B2E-01 grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Partially fill clean application tank with water, add the specified amount of B2E-01, mix, and complete filling with specified quantity of water.
- Use diluted spray solution within 72 hours of mixing. Agitate before each use.
- Clean up extremely dusty sites prior to application.

Use B2E-01 as a fogging concentrate or surface spray for the treatment of stored product pests and other insect pests infesting warehouses, silos, storage bins, or other stored commodity areas. Apply B2E-01 in food processing, food service, food preparation, and food handling establishments including mills, bakeries, restaurants, taverns, industrial buildings, breweries, candy processing, pet food production, grocery stores, modes of transportation (rail cars, ships, and trucks), cereal processing and bottling facilities. Apply B2E-01 to packaged, canned, and bottled foodstuffs, as well as boxes, liners, and pallets. For application of B2E-01 as a fogging space spray, use the following directions.

### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment. Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

### APPLICATION WITH AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml (1/30 oz) per 1000 square feet of surface area or 3 ml (1/10 oz.) per 10,000 cubic feet. Use appropriate spray equipment to achieve uniform coverage.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave room closed for 30 minutes to allow spray mist to settle. Do not remain in the treated areas and ventilate before re-entry. Repeat application as required.



#### APPLICATION AS AN AQUEOUS SPRAY

To prepare a diluted spray solution, partially fill the mixing container with water, add 1 ml (1/30 oz) of B2E-01, mix and complete filling with a total of 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with a low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

When tank mixing B2E-01 with conventional aqueous adulticides, the more stringent label will apply. B2E-01 can also be used or mixed with diatomaceous earth. <sup>Remove</sup>

**(Directions for Use for B2E-01 to prevent the emergence of adult filter flies & non-biting midges)**

### PREVENTS THE EMERGENCE OF ADULT FILTER FLIES AND MIDGES - KEEPS INFESTATIONS UNDER CONTROL

#### INTRODUCTION

B2E-01 is a unique emulsifiable concentrate formulation that controls filter flies (*Psychodidae*), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. B2E-01 contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. B2E-01 does not control adults but prevents the larval stage from developing into flying adults. B2E-01 keeps pest infestations under control by stopping the reproduction cycle, without shutting down your treatment facility. Regular use of B2E-01 prevents these pests from developing into annoying infestations.

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### APPLICATION DIRECTIONS

##### WASTE WATER TREATMENT FACILITY PESTS

Use B2E-01 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

##### WHAT TO EXPECT IN CONTINUOUS FLOW WASTE WATER TREATMENT FACILITIES

To achieve effective results, B2E-01 must be applied to continuous flow systems on a daily basis for 10 days. A gradual reduction in the number of adult pests will be seen over a 7 day period with significant reduction seen after 14 days of treatment. Failure to apply B2E-01 daily may produce erratic results. Very heavy infestations often require slightly longer to achieve the desired control level. Since the mode of action of B2E-01 is to prevent adult emergence, pupa and adults present at the time of initial application will complete their life cycle. Pest populations can be expected to rebound within 2-3 weeks following the last day of treatment.

##### SLUDGE OR SOLID WASTE APPLICATIONS

For sludge solid waste applications, use 3 ounces per million gallons of sludge or solids. Apply dilution until the drying beds have been filled, then stop the application. Make applications at the influent side as the sludge or solids enter into the drying beds. Application of B2E-01 to solids will prevent pest insect emergence and keep infestations under control.

#### APPLICATION METHODS

##### WASTE WATER TREATMENT FACILITIES

Dilute B2E-01 with water prior to use. Apply B2E-01 by use of a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence product dilution. Prepare the desired volume of dilution to apply over a 6-8 hour period, or in cases of sludge drying beds, apply until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of B2E-01 over a 6-8 hour period.



## APPLICATION RATES

### WASTE WATER TREATMENT PESTS

To control waste water pests, apply 3 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply at the influent side over a 6-8 hour period during the lowest flow period of the day. For best results, make the application on a daily basis for 10 days or until suppression of pests is achieved.

### APPLICATION TO WASTE WATER – TRICKLING FILTER

Apply 3 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply the material. Apply at times of low flow periods (typically evening through early morning hours) for 6-8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 10 days or until suppression of pests is achieved.

## MIXING AND HANDLING INSTRUCTIONS:

Partially fill clean application tank with water, add the specified amount of B2E-01, mix, and complete filling with water. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## APPLICATION SITES

### WASTE WATER TREATMENT FACILITIES

Make applications of B2E-01 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem. Make B2E-01 applications as the sewage enters (influent areas) the waste water treatment area. For best results, apply to the influent side.

***(Directions for Use for B2E-01 to prevent the emergence of adult floodwater mosquitoes)***

## PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES

### INTRODUCTION

B2E-01 provides effective levels of S-Methoprene insect growth regulator to prevent the emergence of adult floodwater mosquitoes from treated water. B2E-01 can be applied either diluted in water or used to make granules. Treated larvae continue to develop normally to the pupal stage where they die. B2E-01 prevents the emergence of adult floodwater mosquitoes (*Aedes*, *Ochlerotatus* and *Psorophora*) from treated water.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### APPLICATION DIRECTIONS

Apply B2E-01 to 4th instar floodwater mosquito larvae prior to pupation to prevent adult emergence. Apply B2E-01 in the late afternoon or evening to extend the effective control window. Proper treatment timing is important for best results. For ground and aerial application, use the amount of B2E-01 listed below in sufficient water to give complete coverage. Do not apply when weather conditions will cause drift from the areas to be treated. Use B2E-01 granules to make treatments under windy conditions or to dense vegetation.

**NOTE:** The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

## APPLICATION RATES

Apply 0.5 ounce to 1.5 ounces (15 to 44 ml) of B2E-01 per acre in water. Within this range, use lower rates when applying to shallow water (<1 foot deep) and vegetation is minimal. Use higher application rates when water is deep (>2 foot deep) and vegetation is heavy, or when application conditions require treatments to be made earlier in larval development than recommended. Application of B2E-01 to sites subject to water flow or exchange will diminish the product's effectiveness and requires higher application rates and/or more frequent applications.

liquid/  
granules

Aerial



## MIXING AND HANDLING INSTRUCTIONS

Partially fill clean application tank with water, add the specified amount of **B2E-01**, mix, and complete filling with water. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## APPLICATION SITES

Apply **B2E-01** as directed above to floodwater habitats which support mosquito larval development. Examples of typical sites are: ~~freshwater and salt water marshes, woodland pools and meadows, grassy swales, floodplains, irrigated croplands, pastures and rangeland (without removal of livestock), vineyards, rice fields (including wild rice), fruit and nut orchards, berry fields and bogs, and other natural and manmade depressions where mosquitoes may breed.~~ In dense vegetation or canopy areas, use **B2E-01** to make granules on sand or other carrier following preparation instructions detailed below. Apply **B2E-01** Granules using standard granular dispersal equipment. *which do not runoff...*

## B2E-01 GRANULES:

Granules can be made using washed, dry sand or other carriers. Apply **B2E-01** to the granule quantity to be applied per acre. For example, to apply 1.0 fl. oz./acre dosage rate on 5 pounds of granules per acre: Add 98 pounds of washed dry sand into a small rotary cement mixer. Tilt mixer to an angle 20° above horizontal. Measure out 20 fl. oz. of **B2E-01**, and add to a sprayer equipped with a flat fan nozzle. Pressurize sprayer and turn on mixer. Spray **B2E-01** on the rolling face of the sand until it is evenly dampened. Mix for 2 minutes, then add a drying agent (Microcel E or Hisil 233) as needed, to achieve a dry, free flowing granule. Discharge granules and bag. Apply within 72 hours.

Refer to table below for the number of ounces used to make 100 pound batches of granules applied at different rates per acre.

Dosage Rate Oz./Acre	Granule Application Rate/Acre (Lbs.)	Ounces of B2E-01 applied to granules
0.5	2.5	20
0.5	5.0	10
0.5	10.0	5
1.0	2.5	40
1.0	5.0	20
1.0	10.0	10
1.5	2.5	60
1.5	5.0	30
1.5	10.0	15





Amy Roberts  
<Aroberts@tsgusa.com>

03/23/05 03:14 PM

To Mari Duggard/DC/USEPA/US@EPA

bmintz@b2ecorp.com, Linda

cc Hollis/DC/USEPA/US@EPA, Sheryl

Reilly/DC/USEPA/US@EPA

bcc

Subject B2E-01 (75318-A) - extended PRIA Due Date

Dear Mari:

With this email I wanted to advise that an extended due date of June 28, 2005 for the pending registration B2E-01 (75318-A) is acceptable for B2E Biotech LLC. Let me know if we need to do anything on our end. Otherwise we will await correspondence from EPA on the results of the science review for this pending application.

Best regards,

Amy Plato Roberts  
Technology Sciences Group Inc.  
1101 17th Street, N.W., Suite 500  
Washington, DC 20036  
Tel. (202) 828-8964; Fax (202) 872-0745; Email: [aroberts@tsgusa.com](mailto:aroberts@tsgusa.com)  
Website: [www.tsgusa.com](http://www.tsgusa.com)



Recommendation to Division Directors On Negotiated Due Dates and Denials		
Reg#: 75318-A	Action: B67	PRIA Mandated Time frame: 6 mos.
Submitted by: Mari Duggard		Branch: BPB      Date: 17 Mar 05
Company: B2E Biotech, LLC		
Current Due Date: 28 March 2005		
<p><b>Issue (describe in detail):</b> The registration application is for an Insect Growth Regulator containing 33.6% (S)-Methoprene, to be formulated into pellets for use in tobacco processing and storage facilities. Toxicity and non-target organism data requirements per 40 CFR 158.690 have not been adequately satisfied via the registrant's submitted public literature and waiver rationale. The product performance data (required for control of public health pests) is currently unacceptable, but upgradable to acceptable pending submission and review of requested data and information.</p>		
<p><b>Recommendation (include proposed new due date for renegotiations):</b> The registrant must address the unsatisfied toxicity issues, either through submission of data or revised waiver request rationale. Additionally, the registrant's product performance data requires clarification regarding application techniques, labeled rates and estimation of efficacy, within 3 months: June 28, 2005.</p>		
<p><b>Rationale:</b> This proposed PRIA renegotiation date will allow time for the registrant to submit the required materials, as well as time for Agency review and response to the submission.</p>		
<b>History</b>		
Original Due Date: 29 Dec 2004		
Has due date been renegotiated before: /X/ YES    /___/ NO		
If Yes Provide Complete History: See previous Renegotiation form (attached)		
<p><b>Describe Interactions With Company (describe in detail):</b> The registrant was notified of major deficiencies in the submission through 15 Dec 04 deficiency letter, e-messaging communications throughout the review process, and off-agenda conversations with the registrant at a Pre-registration meeting.</p>		

OK *[Signature]* 3-18-05



Recommendation to Division Directors On Negotiated Due Dates and Denials			
Reg#: 75318-A	Action: B67	PRIA Mandated Time frame: 6 mos.	
Submitted by: Mari Duggard		Branch: BPB	Date: 21 Dec 04
Company: B2E Biotech, LLC			
Current Due Date: 29 Dec 2004			
<b>Issue (describe in detail):</b> The registration application is for an Insect Growth Regulator containing 33.6% (S)-Methoprene, to be formulated into pellets for use in tobacco processing and storage facilities. Toxicity and non-target organism data requirements per 40 CFR 158.690 have not been satisfied, and are required to support registration of this product as it differs in inert composition from its proposed registered source (74032-1).			
<b>Recommendation (include proposed new due date for renegotiations):</b> Per 21 Dec 04 telephone conversation with registrant, a proposed new date of 28 Mar 05 has been suggested and mutually agreed to by both BPPD and registrant.			
<b>Rationale:</b> This proposed PRIA renegotiation date will allow time for the registrant to submit the required materials, as well as time for Agency review and response to the submission.			
<b>History</b>			
Original Due Date: 29 Dec 2004			
Has due date been renegotiated before: <input type="checkbox"/> / YES <input checked="" type="checkbox"/> / NO			
If Yes Provide Complete History:			
<b>Describe Interactions With Company (describe in detail):</b> The registrant was notified of major deficiencies in the submission through 15 Dec 04 deficiency letter, e-messaging communications throughout the review process, and off-agenda conversations with the registrant at a Pre-registration meeting.			
Other Comments:			



# B2E Biotech LLC

500 Mamaroneck Ave. • Suite 201 • Harrison, NY 10528 • USA • Phone: 631-537-9797 • Fax: 631-537-8695

January 14, 2005

U.S. Environmental Protection Agency  
ATTN: Sheryl Reilly, Chief  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511C)  
1801 South Bell Street  
Arlington, VA 22202-4501

EPA File Symbol: 75318-A  
Product Name: B2E-01  
Company Name: B2E Biotech LLC

Subject(s): Response to Deficiency Letter from BPPD dated 12/15/04

Dear Dr. Reilly:

The purpose of this submission is to address deficiencies identified in EPA's letter dated December 15, 2004 for the above referenced product (a copy of the EPA letter is attached). Specific deficiencies identified in the EPA letter are addressed as follows:

- 1) **Biochemical Pesticide Toxicity data** – A waiver has been requested for all Tier 1 toxicity data requirements for an end-use product. A guideline-by-guideline scientific rationale for waiving those requirements is located in the data volume entitled "Response to Tier 1 Biochemical Pesticide Data Requirements for B2E-01."
- 2) **Biochemical Pesticide Product Analysis data** – In its letter EPA states that storage stability data on the formulated end-use product is required. We believe this comment was in error due to the fact that the storage stability data requirement was addressed via self-certification, and was rated "Acceptable" by EPA. Refer to pages 2 and 5 of the product chemistry Data Evaluation Record (DER) for B2E-01.
- 3) **Confidential Statement of Formula (CSF)** – A revised CSF is enclosed that addresses all comments listed in the EPA deficiency letter.
- 4) **Product Performance Data** – No deficiencies for the product performance data submitted for B2E-01 were listed in the EPA letter; however, upon review of the DERs for B2E-01 it is clear that the two submitted studies were rated as "Supplemental, but Upgradeable." As such, we would like to take this opportunity to address the deficiencies noted in the DERs for B2E-01.



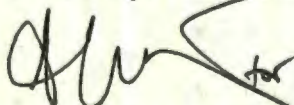
The science reviewer's primary deficiency noted for the two studies submitted was regarding the correlation of the application rate tested with the rate listed on the draft product label. A secondary deficiency was the comment that the study reports do not describe the application techniques.

Attached to this cover letter you will find two addendums to the submitted efficacy studies, which confirm that the rate testing in the studies correlates to the application rate listed in the draft product label. Further, the attached addendums provide a description of the application techniques and address a comment by the EPA reviewer on the use of higher application rates for areas of deep water and/or dense vegetation.

- 5) **Product Label** – Five (5) copies of a revised label are include which make minor modifications to the use directions for application to mushroom culture.

With this submission we believe we have addressed all of the deficiencies identified by EPA. Should there be any questions or comments, I can be contacted directly by phone (631-537-9797) or email (bmintz@b2ecorp.com).

Sincerely,



William K. Mintz  
Manager

encl.



TRANSMITTAL DOCUMENT

1. Submitter:

B2E Biotech LLC  
500 Mamaroneck Ave.  
Harrison, NY 10528

2. Subject: Corrections to Deficiency Letter Dated December 15, 2004  
75318-A [B2E-01] (End Use Product)

3. Transmittal Date: January 14, 2005

4. List of Submitted Documents:

**Vol. 1**

Administrative Materials

Application Form (8570-1)  
Copy of Agency letter response to PRIA dues (12/22/04)  
Copy of Agency Deficiency Letter (12/15/04)  
Cover Letter  
Revised CSF

46445801

**Vol. 2**

Response to Tier I Biochemical Pesticide Data Requirements  
for B2E-01

Company Official: William K. Mintz, Manager

Company: B2E Biotech LLC

Company Contact: William K. Mintz Phone #: 631-537-9797

**Addendum To:**

**Reject (02)** Assessment of B2E-01 insect growth regulator EC (33.6% AI) formulation against  
*Ochlerotatus taeniorhynchus* in small plot field studies, 2003 (MRID No. 462254-07).

**Reject (03) Addendum To:**

Field Evaluation of B2E-01 against the Floodwater Mosquito *Psorophora columbiae* in  
Outdoor Microcosms (MRID No. 463503-01).





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 21, 2005

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

B2E BIOTECH LLC  
500 MAMARONECK AVENUE, SUITE 201  
HARRISON, NY 10528

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 14-JAN-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Studies 2 - 3 were all rejected for the following reasons/s:

\* Whenever you submit information to supplement a previously submitted study--whether at your own initiative or in response to a specific request by EPA--it must be presented in the format required by PR Notice 86-5. Submit three complete copies under an appropriate transmittal document, including supplemental information for only one study in each binding, and clearly identifying the previously submitted study to which it is a supplement on the title page. See page 7 of the notice for further guidance.



# B2E Biotech LLC

500 Mamaroneck Ave. • Suite 201 • Harrison, NY 10528 • USA • Phone: 631-537-9797 • Fax: 631-537-8695

January 14, 2005

U.S. Environmental Protection Agency  
ATTN: Sheryl Reilly, Chief  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511C)  
1801 South Bell Street  
Arlington, VA 22202-4501

EPA File Symbol: 75318-A  
Product Name: B2E-01  
Company Name: B2E Biotech LLC

**Subject(s): Response to Deficiency Letter from BPPD dated 12/15/04**

Dear Dr. Reilly:

The purpose of this submission is to address deficiencies identified in EPA's letter dated December 15, 2004 for the above referenced product (a copy of the EPA letter is attached). Specific deficiencies identified in the EPA letter are addressed as follows:

- 1) **Biochemical Pesticide Toxicity data** – A waiver has been requested for all Tier 1 toxicity data requirements for an end-use product. A guideline-by-guideline scientific rationale for waiving those requirements is located in the data volume entitled "Response to Tier 1 Biochemical Pesticide Data Requirements for B2E-01."
- 2) **Biochemical Pesticide Product Analysis data** – In its letter EPA states that storage stability data on the formulated end-use product is required. We believe this comment was in error due to the fact that the storage stability data requirement was addressed via self-certification, and was rated "Acceptable" by EPA. Refer to pages 2 and 5 of the product chemistry Data Evaluation Record (DER) for B2E-01.
- 3) **Confidential Statement of Formula (CSF)** – A revised CSF is enclosed that addresses all comments listed in the EPA deficiency letter.
- 4) **Product Performance Data** – No deficiencies for the product performance data submitted for B2E-01 were listed in the EPA letter; however, upon review of the DERs for B2E-01 it is clear that the two submitted studies were rated as "Supplemental, but Upgradeable." As such, we would like to take this opportunity to address the deficiencies noted in the DERs for B2E-01.



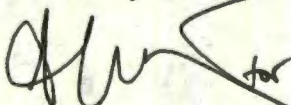
The science reviewer's primary deficiency noted for the two studies submitted was regarding the correlation of the application rate tested with the rate listed on the draft product label. A secondary deficiency was the comment that the study reports do not describe the application techniques.

Attached to this cover letter you will find two addendums to the submitted efficacy studies, which confirm that the rate testing in the studies correlates to the application rate listed in the draft product label. Further, the attached addendums provide a description of the application techniques and address a comment by the EPA reviewer on the use of higher application rates for areas of deep water and/or dense vegetation.

- 5) **Product Label** – Five (5) copies of a revised label are include which make minor modifications to the use directions for application to mushroom culture.

With this submission we believe we have addressed all of the deficiencies identified by EPA. Should there be any questions or comments, I can be contacted directly by phone (631-537-9797) or email (bmintz@b2ecorp.com).

Sincerely,



William K. Mintz  
Manager

encl.



TRANSMITTAL DOCUMENT

1. Submitter:

B2E Biotech LLC  
500 Mamaroneck Ave.  
Harrison, NY 10528

2. Subject: Corrections to Deficiency Letter Dated December 15, 2004  
75318-A [B2E-01] (End Use Product)

3. Transmittal Date: January 14, 2005

4. List of Submitted Documents:

**Vol. 1**

Administrative Materials

Application Form (8570-1)  
Copy of Agency letter response to PRIA dues (12/22/04)  
Copy of Agency Deficiency Letter (12/15/04)  
Cover Letter  
Revised CSF

46445801

**Vol. 2**

Response to Tier I Biochemical Pesticide Data Requirements  
for B2E-01

Company Official: William K. Mintz, Manager

Company: B2E Biotech LLC

Company Contact: William K. Mintz Phone #: 631-537-9797

**Addendum To:**

**Reject (02)** Assessment of B2E-01 insect growth regulator EC (33.6% AI) formulation against  
*Ochlerotatus taeniorhynchus* in small plot field studies, 2003 (MRID No. 462254-07).

**Reject (03) Addendum To:**

Field Evaluation of B2E-01 against the Floodwater Mosquito *Psorophora columbiae* in  
Outdoor Microcosms (MRID No. 463503-01).



## Volume 1 of 3

## TRANSMITTAL DOCUMENT

1. Submitter:

B2E Biotech LLC  
500 Mamaroneck Ave.  
Harrison, NY 10528


2. Subject: Submission of Supplemental Information to Support Registration of:

**B2E-01 (File Symbol 75318-A)**

3. Transmittal Date: January 24, 20054. List of Submitted Documents:

<b>Vol. 1</b>	Transmittal Document
<b>Vol. 2</b>  <b>46453001</b>	Supplemental Product Performance Data for MRID No. 462254-07
<b>Vol. 3</b>  <b>46453002</b>	Supplemental Product Performance Data for MRID No. 463503-01

Company Official: William K. Mintz, Manager  
Company: B2E Biotech LLC  
Company Contact: William K. Mintz  
Phone #: 631-537-9797  
E-Mail: bmintz@b2ecorp.com





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

William K. Mintz  
B2E Biotech, LLC  
500 Mamaroneck Ave., Suite 201  
Harrison, NY 10528

DEC 22 2004

756385 | B07  
MD | 13

RE: Agency response to your 21 Dec 04 offer to negotiate PRIA due dates for pending Registration Applications

B2E-01 (EPA File Symbol 75318-A)

B2E-02 (EPA File Symbol 75318-R)

B2E-03 (EPA File Symbol 75318-E)

B2E-04 (EPA File Symbol 75318-G)

B2E-05 (EPA File Symbol 75318-U)

B2E-06 (EPA File Symbol 75318-L)

Application dated: 22 April 2004

Dear Mr. Mintz:

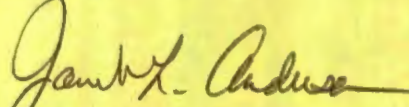
Your offer to negotiate the due dates of your pending registration applications has been accepted, to allow time for the deficiencies identified in previous correspondence to be addressed and corrected. Per our discussion on 21 Dec 04, the new PRIA due dates (pending receipt of your re-submission no later than 14 Jan 05) are as follows:

28 Feb 2005: B2E-02 (75318-R)  
B2E-03 (75318-E)  
B2E-05 (75318-U)  
B2E-06 (75318-L)

28 Mar 2005: B2E-04 (75318-G)  
B2E-01 (75318-A)

Should you have any questions concerning this action, please contact Mari Duggard at 703-308-0028 or by e-mail at [duggard.mari@epa.gov](mailto:duggard.mari@epa.gov).

Sincerely,

  
Janet L. Andersen, Director  
Biopesticides and Pollution  
Prevention Division (7511C)

CONCURRENCES

SYMBOL	7511c							
SURNAME	DUGGARD							
DATE	22 DEC 04							

96



Recommendation to Division Directors On Negotiated Due Dates and Denials			
Reg#: 75318-A	Action: B67	PRIA Mandated Time frame: 6 mos.	
Submitted by: Mari Duggard		Branch: BPB	Date: 21 Dec 04
Company: B2E Biotech, LLC			
Current Due Date: 29 Dec 2004			
<b>Issue (describe in detail):</b> The registration application is for an Insect Growth Regulator containing 33.6% (S)-Methoprene, to be formulated into pellets for use in tobacco processing and storage facilities. Toxicity and non-target organism data requirements per 40 CFR 158.690 have not been satisfied, and are required to support registration of this product as it differs in inert composition from its proposed registered source (74032-1).			
<b>Recommendation (include proposed new due date for renegotiations):</b> Per 21 Dec 04 telephone conversation with registrant, a proposed new date of 28 Mar 05 has been suggested and mutually agreed to by both BPPD and registrant.			
<b>Rationale:</b> This proposed PRIA renegotiation date will allow time for the registrant to submit the required materials, as well as time for Agency review and response to the submission.			
<b>History</b>			
Original Due Date: 29 Dec 2004			
Has due date been renegotiated before: <input type="checkbox"/> / YES <input checked="" type="checkbox"/> / NO			
If Yes Provide Complete History:			
<b>Describe Interactions With Company (describe in detail):</b> The registrant was notified of major deficiencies in the submission through 15 Dec 04 deficiency letter, e-messaging communications throughout the review process, and off-agenda conversations with the registrant at a Pre-registration meeting.			
Other Comments:			



# B2E Biotech LLC

500 Mamaroneck Ave. • Suite 201 • Harrison, NY 10528 • USA • Phone: 631-537-9797 • Fax: 631-537-8695

December 21, 2004

Janet Andersen  
Director, Biopesticides and Pollution Prevention Division (7511C)  
Office of Pesticide Programs, EPA  
1921 Jefferson Davis Highway  
Arlington, VA 22202

**RE: B2E-02; File Symbol 75318-R  
B2E-03; File Symbol 75318-E  
B2E-04; File Symbol 75318-G  
B2E-05; File Symbol 75318-U  
B2E-06; File Symbol 75318-L  
B2E-01; File Symbol 75318-A**

**Offer to negotiate the PRIA due dates for pending applications**

Dear Dr. Andersen:

Thank you for the guidance provided earlier today on our telephone conference call with Linda Hollis and Gail Tomimatsu. Per our discussion, we are revising the new PRIA due dates to:

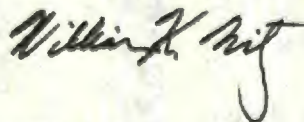
February 28, 2005 - B2E-02; File Symbol 75318-R  
B2E-03; File Symbol 75318-E  
B2E-05; File Symbol 75318-U  
B2E-06; File Symbol 75318-L

March 28, 2005 - B2E-04; File Symbol 75318-G  
B2E-01; File Symbol 75318-A

The above dates are based on B2E submitting responses to the identified deficiencies no later than January 14, 2004. The responses will include revised CSFs and labels, clarification of product chemistry and product performance data, and data waiver rationales. The dates for 75318-G (B2E-04) and 75318-A (B2E-01) are proposed for later than the other products, as B2E-04 and B2E-01 are not as critical to our business plans. Furthermore, B2E understands that if waivers requested (based on two published eco-toxicology) are not granted, the due dates for 75318-U and 75318-G may require renegotiation to a later time.

We look forward to receiving written (either email or hard copy) confirmation of the above. Again, thanks for your consideration.

Sincerely,



William K. Mintz





Linda  
Hollis/DC/USEPA/US@EP  
A

12/17/04 01:27 PM

To Janet Andersen/DC/USEPA/US@EPA  
Mari Duggard/DC/USEPA/US@EPA, Gail  
cc Tomimatsu/DC/USEPA/US@EPA, Russell  
Jones/DC/USEPA/US@EPA

bcc

Subject Fw: Clarification Request & Negotiation Letter - My  
comments



Janet: My comments in response to the Mintz email is as follows:

#1. The last para of page 3 talks about the mup, and the fact that we re-reviewed the data generated on the source Hartz product and that it did not fully satisfy aquatic uses. We indicated what data would be needed for the MUP, i.e., All tier studies. tox, non target and product chem. If this is not specific enough for bill, the Answer is:

[http://www.epa.gov/opptsfrs/OPPTS\\_Harmonized/850\\_Ecological\\_Effects\\_Test\\_Guidelines/Drafts/](http://www.epa.gov/opptsfrs/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Drafts/)

[http://www.epa.gov/opptsfrs/OPPTS\\_Harmonized/850\\_Ecological\\_Effects\\_Test\\_Guidelines/index.html](http://www.epa.gov/opptsfrs/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/index.html)

[http://www.epa.gov/opptsfrs/OPPTS\\_Harmonized/880\\_Biochemicals\\_Test\\_Guidelines/Series/](http://www.epa.gov/opptsfrs/OPPTS_Harmonized/880_Biochemicals_Test_Guidelines/Series/)

#### Hazard to Nontarget Organisms

The information required to assess hazards to nontarget organisms are derived from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, subacute, reproduction, simulated field, and full field studies arranged in a hierarchical or tier system that progresses from the basic laboratory tests to the applied field tests. The results of each tier of tests must be evaluated to determine the potential of the pesticide to cause harmful effects and to determine whether further testing is required. A purpose common to all data requirements is to help determine the need for (and appropriate wording for) precautionary label statements to minimize the potential harm to nontarget organisms.

#### Short-term Studies

The short-term acute and subchronic laboratory studies provide basic toxicity information that serves as a starting point for the hazard assessment. These data are used to:

- establish acute toxicity levels of the active ingredient to the test organisms;
- compare toxicity information with measured or estimated pesticide residues in the environment in order to assess potential effects on fish, wildlife and other nontarget organisms; and
- indicate whether further laboratory and/or field studies are needed.

#### Long-term and Field Studies

Additional studies (i.e., avian, fish, and invertebrate reproduction, lifecycle studies, and plant field studies) may be required when basic data and environmental conditions suggest possible problems. Data from these studies are used to:

- estimate the potential for chronic effects, taking into account the measured or estimated residues in the environment; and
- determine if additional field or laboratory data are



necessary to further evaluate hazards. Simulated field and/or field data are used to examine acute and chronic adverse effects on captive or monitored fish and wildlife populations under natural or near-natural environments.

Such studies are required only when predictions as to possible adverse effects in less extensive studies cannot be made, or when the potential for harmful effects is high.

Specific studies, guideline and description can be found in the websites listed above.

The mysid shrimp study and aquatic studies that Wellmark did in support of their registrations were required because their products were slow release productst. Slow release as defined by the Agency were those products such as the briquettes which would remain in the water for 30 days minimal. B2E does have these products. I do not have the label and so I am unsure which. They also are coming in with products with release times in excess of 30 days per the Oct. 7th meeting with Mintz and Roberts. However, this was only one of the reasons why EPA asked that Wellmark conduct these studies. Therefore, 30 day release products or those exceeding 30 days would qualify as slow release and Bill can determine which of his products fall within this category.

I believe that we have provided Bill Mintz with the necessary and specific information needed to resubmit. We informed him that he 1) needed to address the tier 1 studies for non target, listed in 40 CFR but a description of the harmonized guidelines, exact name of the studies can be found in the websites above.

This information provides Mintz with what requirements need to be satisfied and so his explanation for why each journal articl satisfies the data requirment can be written with direction.

The Agency has provided Bill with a cursory review of the information he provided via email as to if the studies in the literature would support waiver requests for non-target data requirements. We were clear in our letter that we would accept rationales if the argument was fully justified. I think we were clear to him that the articles he emailed could "in principle" be



used to support a waiver request only if we were able to pull the germain, salient points from the articles to build his case. We are not at liberty to say "yes, these articles are acceptable" without looking at the entire package.

Finally, his last comment. Page 6 (per the copy I have) refers to -E (water soluble pouch, water and food use sites), this is the product that contains an inert which may be an irritant. The deficiencies for E seem identical to the deficiencies in G and this may be in error.

Regards,

Linda A. Hollis  
Team Leader  
Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division  
(703) 308-8733  
(703) 308-0115 fax

----- Forwarded by Linda Hollis/DC/USEPA/US on 12/17/2004 12:32 PM -----

Bill Mintz  
<bmintz@b2ecorp.  
com>

12/17/2004 11:54  
AM

To  
Janet Andersen/DC/USEPA/US@EPA  
cc  
Sheryl Reilly/DC/USEPA/US@EPA,  
Linda Hollis/DC/USEPA/US@EPA,  
Mari Duggard/DC/USEPA/US@EPA,  
Gail Tomimatsu/DC/USEPA/US@EPA,  
Amy Roberts <aroberts@tsgusa.com>  
Subject  
Clarification Request &  
Negotiation Letter

Dear Dr. Andersen,

After reviewing the deficiency letter for 75318-R, -E, -G, -U, -L and -A, several items were identified that need Agency clarification:

- 1) a. In the last paragraph on page 3 (Item #2), it states that the Agency has concluded that "non-target organism data requirements have not been fully satisfied for the proposed aquatic use sites". We raised the question of what the specific



requirements would be at our meeting on October 7, 2004 and were told that they would be contained in the deficiency letter. They are not specified in the deficiency letter and so we still are uncertain of the requirements. What are the exact study(ies) required, identified by OPPTS guideline number?

b. Another question raised at the October 7 meeting was which products would need non-target organism data. In the 1991 RED, it stated that only slow-release products used in estuarine environments would require further (unspecified) data. Also, the definition of "slow-release" was not clearly defined and B2E requested guidance. We were told that this also would be contained in a deficiency letter. Can you please identify the products that are considered "slow-release" and for which there an ecological toxicity concern?

c. The deficiency letter acknowledges (last paragraph on page 3-Item #2) receipt of the November 5, 2004 email containing 2 published studies. The letter further states that these should be formally submitted with "an explanation of why each journal article satisfies a particular requirement...". We still do not know which requirements need to be satisfied. Additionally, in the November 5 email, we requested an indication of whether these published studies were acceptable in principle to fulfill any data requirements. If the Agency were able to give an indication on whether or not the published articles could be acceptable in principle (with the appropriate accompanying waiver requests and scientific rationale), this would be helpful.

2) On page 6, it appears that the entire page is referring to 75318-G and not 75318-E. However, B2E does need to know if there are any deficiencies with the submitted studies supporting 75318-E.

With the clarification of the above items B2E will be able to work with the Agency to expeditiously negotiate a new PRIA due date with consideration of the needs of both the BPPD and B2E. In an effort to move the process forward and to comply with the current due date, a letter is attached to this email formally requesting proposed extended PRIA due dates.

Sincerely,  
William Mintz (See attached file: PRIA Negotiation Letter 01.pdf)



PRIA Negotiation Letter 01.pdf



FedEx Express



United States  
Environmental Protection Agency  
Washington, DC 20460

Pickup # 11

## PROCUREMENT REQUEST/ORDER

Bank Card	1. Name of Originator <b>Mari Duggard</b>		2. Date of Requisition <b>22 DEC 2004</b>	
	3. Mail Code <b>7511C</b>	4. Telephone Number <b>703-308-8713</b>	5. Date Item Required <b>ASAP</b>	
6. Signature of Originator 		7. Recommended Procurement Method <input type="checkbox"/> Competitive <input type="checkbox"/> Other than full and open competition <input type="checkbox"/> Sole source small purchase		
8. Deliver To (Project Officer)	9. Address EPA, Rm. 910 1921 Jefferson Davis Hwy., Arlington, VA 22202		10. Mail Code <b>7511C</b>	11. Telephone Number <b>308-8712</b>
12. Suggested Source (Name, Address, ZIP Code, Phone/Contact) <b>Federal Express 1-800-463-3339</b>		13. Amount of money committed is: <input type="checkbox"/> Increase <input type="checkbox"/> Extension <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Original <input type="checkbox"/> Cancellation		14.

## 15. Approvals

a. Branch/Office  Phil Hutton, Chief, MPB or Sheryl Reilly, Chief, BPB	Date	d. Property Management Officer/Designee	Date
b. Division/Office  Janet L. Andersen, Director, BPPD	Date <b>12/22/04</b>	e. Other (Specify)	Date
c. Funds listed in Block 26 and Block 14 (if any) are available and reserved (Signature and phone number of Certifying Official)  Pamela C. Landis		Phone  308-7013	Date

## 25. Schedule

Item Number (a)	Supplies or Services (b)	Quantity Ordered (c)	Unit (d)	Estimated Unit Price (e)	Estimated Total Cost
	Pickup/Delivery to: - William Mintz BZE corporation P.O. Box 1483 Bridgehampton, NY 11932-1483				

## 26. Financial and Accounting Data

Line	DCN (Max 6)	Budget FYs (Max 4)	Appropriation Code (Max 3)	Budget Org Code (Max 7)	Program element (Max 3)	Object Class (Max 4)	SFO
1						2220	<input type="checkbox"/> (Max 2)
2							
3							

Line	Amount (Max 1)	Cost (Max 1)	Site/Project (Max 3)	Cost Org Code (Max 7)
1				
2				
3				





**Biopesticides and  
Pollution Prevention  
Division**

**FAX**

December 15, 2004

Pages: 12

To: William Mintz  
B2E Biotech LLC

From: Mari Duggard  
US Environmental Protection Agency  
Office of Pesticide Programs  
Biopesticides & Pollution Prevention Division (7511C)  
1200 Pennsylvania Ave NW, Washington, DC 20460  
703-308-0028 (phone) 703-308-7026 (fax)

Message: Deficiency letter for B2E-01 thru B2E-06



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

DEC 15 2004

William K. Mintz  
B2E Biotech, LLC  
500 Mamaroneck Ave., Suite 201  
Harrison, NY 10528

RE: Your applications for six (S)-Methoprene registrations dated 22 April 2004  
EPA File Symbol 75318-R; Product Name: B2E-02 (End use product, water soluble pouch, aquatic & food crop use sites)  
EPA File Symbol 75318-E; Product Name: B2E-03 (End use product, water soluble pouch, aquatic & food crop use sites)  
EPA File Symbol 75318-G; Product Name: B2E-04 (End use product, pellets, aquatic & food crop use sites)  
EPA File Symbol 75318-U; Product Name: B2E-05 (End use product, briquet, aquatic & food crop use sites)  
EPA File Symbol 75318-L; B2E-06 (Manufacturing Use Product)  
EPA File Symbol 75318-A; B2E-01 (end use product for use in tobacco processing and storage facilities)

Dear Mr. Mintz:

The applications referred to above, submitted in connection with registration under FIFRA section 3(c)(5) have been reviewed by BPPD and deficiencies have been identified. These products are interrelated which has made the review more complex, but it seems best at this time to send one letter to explain the deficiencies and provide options for your company as a response. I am willing, as are others in BPPD, to discuss each of these products individually or as a group. These products all have a PRIA decision date of December 29, 2004. If the deficiencies cannot be addressed by B2E and reviewed by EPA by this date, EPA will have to issue a letter that we cannot grant your applications. However, OPP is willing to negotiate due dates for each of these products individually, or as a group where appropriate, that can allow you time to provide the needed information. An alternative you have mentioned is the removal of certain use sites at this time. This may be an option for some products, but all other deficiencies would have to be addressed as well. I will be available throughout the month of December to discuss each and/or all of these applications with you and most of the staff will be here too so we are ready and willing to work with you. You have the option to provide waiver requests for the required studies. Each guideline data requirement must be addressed individually with a scientifically valid rationale. The Agency reserves the right to require that you submit the data, in the event that the submitted waiver requests are determined unacceptable.

CONCURRENCES

SYMBOL	7511c	7511c					
SURNAME	DUGGARD	Ruff					
DATE	14 DEC 04	15 DEC 04					

106



(2 front pages to  
preserve concurrence)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

William K. Mintz  
B2E Biotech, LLC  
500 Mamaroneck Ave., Suite 201  
Harrison, NY 10528

RE: Your applications for six (S)-Methoprene registrations dated 22 April 2004  
EPA File Symbol 75318-R; Product Name: B2E-02 (End use product, water soluble pouch, aquatic & food crop use sites)  
EPA File Symbol 75318-E; Product Name: B2E-03 (End use product, water soluble pouch, aquatic & food crop use sites)  
EPA File Symbol 75318-G; Product Name: B2E-04 (End use product, pellets, aquatic & food crop use sites)  
EPA File Symbol 75318-U; Product Name: B2E-05 (End use product, briquet, aquatic & food crop use sites)  
EPA File Symbol 75318-L; B2E-06 (Manufacturing Use Product)  
EPA File Symbol 75318-A; B2E-01 (end use product for use in tobacco processing and storage facilities)

Dear Mr. Mintz:

The applications referred to above, submitted in connection with registration under FIFRA section 3(c)(5) have been reviewed by BPPD and deficiencies have been identified. These products are interrelated which has made the review more complex, but it seems best at this time to send one letter to explain the deficiencies and provide options for your company as a response. I am willing, as are others in BPPD, to discuss each of these products individually or as a group. These products all have a PRIA decision date of December 29, 2004. If the deficiencies cannot be addressed by B2E and reviewed by EPA by this date, EPA will have to issue a letter that we cannot grant your applications. However, OPP is willing to negotiate due dates for each of these products individually, or as a group where appropriate, that can allow you time to provide the needed information. An alternative you have mentioned is the removal of certain use sites at this time. This may be an option for some products, but all other deficiencies would have to be addressed as well. I will be available throughout the month of December to discuss each and/or all of these applications with you and most of the staff will be here too so we are ready and willing to work with you. You have the option to provide waiver requests for the required studies. Each guideline data requirement must be addressed individually with a scientifically valid rationale. The Agency reserves the right to require that you submit the data, in the event that the submitted waiver requests are determined unacceptable.

Although this letter is long, it addresses each product and shows the connections (or the lack of



connections) between products and where there are possibilities to bridge data. It is your obligation to request a waiver due to bridging data and explain why that is scientifically valid. If we do not find the waiver justification valid, the study(ies) will have to be conducted and reviewed before EPA can make a decision on your application(s). Please feel free to contact me, but understand that I will rely on my staff who have more expertise with these products.

#### 75318-A End Use Product

This product is an end use product for tobacco facilities which relies on a technical methoprene product registered by Hartz Corporation (74032-1) containing 95.5% active ingredient. Your proposed product consists of 33.6% of the active ingredient and 66.4% intentionally added inert ingredients.

While you have claimed formulator's exemption, which under FIFRA section 3(c)(2)(D) exempts you from the requirement to submit or cite data pertaining to the safety of the active ingredient because you are using an EPA registered source, you must still meet the data requirements for the formulated product. The Agency does allow for bridging of toxicology and non-target organism data when the studies are conducted on the test material of higher concentration than that of the concentration in the pending product. However, this method of data support (bridging from the source product) will not be acceptable in this case for the reason below:

Your product contains inert ingredients that are not present in the source product for which there may be toxicological concerns that cannot be determined without testing or must be explained by a data waiver request for each data requirement individually.

Based on the information presented above, the following data and/or information are required to support registration of the proposed end use product:

1. ***Biochemical pesticide toxicology data required***

All Tier I toxicity studies (required) - see footnotes in the data tables for 158.690 for test substance and criteria for conditionally required data. You may request waivers individually for each Tier 1 data requirement. If you do not believe that the inerts change the toxicity categories for the Tier 1 data requirements, you must submit a scientific rationale for EACH data requirement.

2. ***Biochemical pesticide product analysis data required***

Storage stability data on the formulated end use product. Storage stability data conducted on a registered source of a Technical Grade Active Ingredient (TGAI) can be used to support the registration of an end use product when the two are substantially similar in composition. However, as discussed above, your formulated end use product differs substantially from the Hartz source product. Thus, storage stability data must be generated on this end use product to support registration, or you must request a waiver and provide a scientific rationale why these data are not needed.

3. ***Confidential Statement of Formula (CSF):***

- a. Identify the actual chemical names and CAS # used in the formulation of the product. Currently, the proprietary names of the chemicals [REDACTED] are not sufficient. These components and their CAS # must be listed individually in column 10.
- b. Correct the spelling of the chemical [REDACTED] on the CSF.



No product label comments or edits are included for this product as data requested above may impact the label claims or precautionary language. A full label review will be conducted and any changed, if needed will be provided to you upon review of the data.

#### 75318-L Manufacturing Use Product

This proposed product would serve as the manufacturing use product (MUP) for 4 of the other end use products included in your April 22, 2004 application and may serve for other end use products in the future. Your application for a proposed MUP proposes to rely on data submitted in support of registration for a Methoprene MUP (74032-1) containing 95.5% active ingredient. While you have claimed formulator's exemption, which under FIFRA section 3(c)(2)(D) exempts you from the requirement to submit or cite data pertaining to the safety of the active ingredient because you are using an EPA registered source, you must still meet the data requirements for the formulated product(s). The Agency does allow for bridging of toxicology and non-target organism data in some circumstances when the studies are conducted on the test material of higher concentration than that of the concentration in the pending product. However, this method of data support (bridging from the source product) will not be acceptable in this case for the following reasons:

1. Your proposed MUP consists of 40% of the active ingredient and 60% intentionally added inert ingredients. that are not present in the source product for which there may be toxicological concerns that cannot be determined without testing. Therefore, data requirements per 40 CFR 158.690 must be satisfied with regards to toxicity and non-target organisms. If you believe that any of the Tier I tests should be waived, you must submit a waiver request and appropriate rationale for each guideline requirement.
2. Upon reexamination of the data supporting the Hartz source product (74032-1) on which your proposed MUP relies, the Agency concludes that non-target organism data requirements have not been fully satisfied for the proposed aquatic uses. BPPD notes that on November 5, 2004, you e-mailed to some BPPD staff two studies from the public literature which may support the proposed aquatic uses for your product. However, you need to formally submit quality copies of these studies, summaries of each study, an explanation of why each of the journal articles satisfies a particular data requirement, and a request to waive each of the data requirements. Likewise aquatic uses on any of the pending (or future) end use products formulated from this proposed MUP are not supported unless acceptable Tier I non-target aquatic organism data (i.e., chronic mysid shrimp study and non-target fish study) or acceptable data waiver and scientific rationales are submitted. The test material for the non-target organism data may be bridged when the inert ingredients in the end use formulations are water or simple dilutions of the other ingredients already in the MUP. Aquatic non-target testing may be necessary for end use products where inert ingredients other than those present in the MUP are used.

Based on the information presented above, the following data/ and or information are required to support registration of the proposed MUP. In addition, data required to support any end use product which intends to rely on the pending MUP (75318-L) as the source will be determined based on the formulation of the end use product and whether or not data submitted on the MUP can be bridged in support of the end use product.

#### ***Biochemical pesticide toxicology data required***

All Tier I toxicity studies (required) - see footnotes for test substance and criteria for conditionally



required data

***Biochemical pesticide non target organism data required***

All Tier I toxicity studies (required) - see footnotes for test substance and criteria for conditionally required data

***Biochemical pesticide product analysis data required***

Storage stability data on the manufacturing use product (see explanation #1 above)

No product label comments or edits are included for this product as data requested above may impact the label claims or precautionary language. A full label review will be conducted and any changed, if needed will be provided to you upon review of the data.

**75318-R End use product, water soluble pouch, aquatic & food crop use sites**

Your application for this proposed end use product (EP), B2E-02 proposes to rely (by formulator's exemption) on your pending MUP (75318-L) for which the core data deficiencies listed above need to be addressed before a decision on the registration of this product can be made. The Agency does allow for bridging of toxicology and non-target organism data when the studies are conducted on the test material of higher concentration than that of the concentration in the pending product. This method of data support (bridging from the source pending product) will be acceptable in this case since this end use product is a dilution of the test material (formulated manufacturing use product). However, if the formulation for this end use product is changed such that it does not represent a dilution of the pending source but contains additional inerts which are not a part of the manufacturing use product (pending source), bridging of data may not be allowed and you may be required to generate all required data on the alternate formulation. Therefore, pending approval of the source MUP, the following will be required at this time to support registration of this formulation:

1. ***Confidential Statement of Formula (CSF) deficiencies:***

In box 10, change the CAS# for the [REDACTED].

2. ***Product Chemistry Data:***

Clarify the statement, "Adjust the B2E-06 to obtain 40% active ingredient, if necessary." (found on page three of MRID 46115603 entitled "Description of the Formulation Process") Based on the label and data for the MUP, the concentration of the active ingredient in the MUP should remain at 40% (B2E-06) without the need for adjustment.

3. ***Product Performance Data:***

Product performance studies must be conducted according to the Directions for Use as specified on the label. Your product label includes claims against a public health pest, and must be tested in the same manner it is intended to be used by a consumer. The application rates used in the submitted studies are not within the recommended range on the label. You must establish equivalence between rates of application stated in the studies and rates recommended on the product label, as well as verify that the water solution tested is actually the pending product.

4. ***Product Label Review:*** (refer to enclosed annotated label).

a. Please indicate the net content/ weight of the product.



- b. Please provide the appropriate Establishment Number on the product label.
- c. Please revise the Environmental Hazards statement to read:  
*"Do not contaminate water when disposing of equipment washwaters or rinsate."*
- d. It is preferred by the Agency that the Storage & Disposal section of a product label be displayed in boxed format, so that it can be easily distinguished from other labeling language.  
  
 Please revise the container disposal statement to read:  
*"Dispose of the empty outer foil pouch in the trash, as long as WSP is unbroken."*
- e. Please incorporate the phrase, "To the fullest extent permitted by law," to your warranty statement, as it currently includes overly broad language regarding the limitations of liability.
- f. Certain sites as listed on your proposed product label are not supported by the data you submitted. You must either provide the data or cite other data available to EPA, including certification of an offer to pay to rely on other data. Please see below for clarification:

Salt water marshes, irrigated cropland, rice fields, etc - your label contains several use sites which support aquatic non/food crop use patterns. Wildlife and aquatic organisms data requirements must be addressed. It is the Agency's understanding that you anticipate submission of data which may support these use sites. However at this time, and until Agency receipt and approving review of such data, the above referenced use sites are unacceptable on the product label.

Please note that labeling comments are subject to change per review of requested materials.

75318-E End use product, water soluble pouch, aquatic & food crop use sites

Your application for the proposed end use product (EP) B2E-03 proposes to rely (by formulator's exemption) on your pending MUP (75318-L) for which the core data deficiencies listed above need to be addressed before a decision on the registration of this product can be made. The Agency does allow for bridging of toxicology and non-target organism data when the studies are conducted on the test material of higher concentration than that of the concentration in the pending product and the additional inert ingredients are not likely to increase the potential for adverse effects or raise toxicological concerns. This method of data support (bridging from the source pending product) will be not acceptable in this case since your proposed end use product varies substantially in inert composition from the source product. The submitted CSF lists certain inert ingredients (including a likely skin irritant), which alter the formulation such that the proposed end-use product formulation is not substantially similar to the source product (75318-L) to rely on its data with regards to toxicity and non-target organisms data requirements. Therefore, pending acceptance of the source MUP for registration, the following will be required at this time to support registration of this formulation:

1. **Biochemical Pesticide Toxicity data**

You must submit product-specific data on your proposed end use product, or an acceptable waiver request which provides scientific rationale that justifies a waiver of each data requirement (40 CFR



158.690.) Because of the presence of a likely skin irritant in the formulation of this product, the Agency expects that a dermal irritation and an acute dermal toxicity study will be required although you have the option of requesting a waiver. If the waivers for such guidelines are determined to be unacceptable, the required studies will have to be conducted and reviewed before the Agency can make a decision on your application.

2. **Confidential Statement of Formula (CSF) deficiencies:**

- a. [REDACTED]. In order to correctly identify the actual composition of the [REDACTED], please list all three of these ingredients, their CAS numbers, and their percentage in the composition in the same box (box 10).
- b. The CAS# listed for the [REDACTED] on the CSF is incorrect, as it currently reflects the CAS # for [REDACTED]. Please revise.

3. **Product Chemistry Data:**

Please clarify the statement, "Adjust the B2E-06 to obtain 40% active ingredient, if necessary." (found on page three of MRID 46115003 entitled "Description of the Formulation Process"). Based on the label and data for the MUP, the concentration of the active ingredient in the MUP should remain at 40% (B2E-06) without the need for adjustment.

4. **Product Performance Data:**

- a. The submitted studies exhibit that lasting efficacy of the product is variable with rates and species of mosquito. The data from MRID 461150-06 concludes that the product was effective (based on OPPTS guideline 810.3400, which requires 95% minimum population reduction) for up to 7 days post-treatment. Data derived from the submitted studies do not support lasting efficacy of the product for 30 days as stated on the product label. You must either amend your label to reflect the efficacious period exhibited in the study, or re-submit data which proves lasting efficacy for 30 days or more.
- b. Please clarify the discrepancy between data values reported on page 6 and Table 1 of MRID 461150-06 for average percent IEs. The text reports averages of 40 and 60 percent for IE of larvae introduced 28 and 35 days, respectively. This information appears inverted in Table 1, where average IE for larvae introduced 28 and 35 days post treatment is 60 and 40 percent, respectively.

5. **Product Label Review:** (refer to enclosed annotated label)

- a. Please indicate the net content/ weight of the product.
- b. Please provide the appropriate Establishment Number on the product label.
- c. Please add the "If Swallowed" route of exposure and the labeling language:  
"If Swallowed:



- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

- d. It is preferred by the Agency that the Storage & Disposal section of a product label be displayed in boxed format, so that it can be easily distinguishable from other labeling language.
- e. Please incorporate the phrase, "To the fullest extent permitted by law," to your warranty statement, as it currently includes overly broad language regarding the limitations of liability.
- f. Certain sites as listed on your proposed product label are not supported by the data you submitted. You must either amend your application to remove all aquatic use sites, provide the data, or cite other data available to EPA, including certification of an offer to pay to rely on other data. Please see below for clarification:

Salt water marshes, irrigated cropland, rice fields, etc - your label contains several use sites which support aquatic non/food crop use patterns. Wildlife and aquatic organisms data requirements must be addressed. It is the Agency's understanding that you anticipate submission of data which may support these use sites. However at this time, and until Agency receipt and approving review of such data, the above referenced use sites are unacceptable on the product label.

Please note that labeling comments are subject to change per review of requested materials.

#### 75318-G End use product, pellets, aquatic & food crop use sites

Your application for the proposed end use product B2E-04 proposes to rely (formulator's exemption) on your pending MUP (75318-L) for which the core data deficiencies listed above need to be addressed before a decision on the registration of this product can be made. The Agency does allow for bridging of toxicology and non-target organism data when the studies are conducted on the test material of higher concentration than that of the concentration in the pending product and the additional inert ingredients are not likely to increase the potential for adverse effects or raise toxicological concerns. This method of data support (bridging from the source pending product) will be not acceptable in this case since your proposed end use product varies substantially in inert composition from the source product. The submitted CSF lists certain inert ingredients which alter the formulation such that the proposed end-use product formulation is not substantially similar to the source product (75318-L) to rely on its data with regards to toxicity and non-target organisms data requirements for registration applications. Therefore, pending approval of the source MUP, the following will be required at this time to support registration of this formulation:

1. **Biochemical Pesticide Toxicity data**  
You must submit product-specific data on your proposed end use product, or an acceptable waiver request which provides scientific rationale that justifies a waiver of each data requirement (40 CFR 158.690.) The Agency reserves the right to require that you submit the data, in the event that the submitted waiver requests are determined unacceptable.
2. **Confidential Statement of Formula (CSF) deficiencies:**



- a. [REDACTED]  
[REDACTED]. In order to correctly identify the actual composition of the [REDACTED]  
[REDACTED] please list all three of these ingredients, their CAS numbers, and their percentage  
in the composition in the same box (box 10).
- b. The CAS# listed for the [REDACTED] on the CSF is incorrect, as it currently reflects the  
CAS # for [REDACTED]. Please revise.

3. **Product Chemistry Data:**

Please clarify the statement, "Adjust the B2E-06 to obtain 40% active ingredient, if necessary." (found on page three of MRID 46115003 entitled "Description of the Formulation Process"). Based on the label and data for the manufacturing use product (MUP), the concentration of the active ingredient in the MUP should remain at 40% (B2E-06) without the need for adjustment.

4. **Product Performance Data:**

- a. The submitted studies demonstrate that lasting efficacy of the product is variable with application rates and species of mosquito. The data from MRID 461150-06 concludes that the product was effective (based on OPPTS guideline 810.3400, which requires 95% minimum population reduction) for up to 7 days post-treatment. Data derived from the submitted studies do not support lasting efficacy of the product for 30 days as claimed on the product label. You must either amend your label to reflect the efficacious period exhibited in the study, or re-submit data which supports the label claims.
- b. Please clarify the discrepancy between data values reported on page 6 and Table 1 of MRID 461150-06 for average percent IEs. The text reports averages of 40 and 60 percent for IE of larvae introduced 28 and 35 days, respectively. This information appears inverted in Table 1, where average IE for larvae introduced 28 and 35 days post treatment is 60 and 40 percent, respectively.

5. **Product Label Review:** (refer to enclosed annotated label)

- a. Please indicate the net content/ weight of the product.
- b. Please provide the appropriate Establishment Number on the product label.
- c. Please add the "If Swallowed" route of exposure and the labeling language:  
"If Swallowed:  
-Call a poison control center or doctor immediately for treatment advice.  
-Have person sip a of water if able to swallow.  
-Do not induce vomiting unless told to by a poison control center or doctor.  
-Do not give anything to an unconscious person.
- d. It is preferred by the Agency that the Storage & Disposal section of a product label be displayed in boxed format, so that it can be easily distinguishable from other labeling language.



- e. Please incorporate the phrase, "To the fullest extent permitted by law," to your warranty statement, as it currently includes overly broad language regarding the limitations of liability.
- f. Certain sites as listed on your proposed product label are not supported by the data you submitted. You must either amend your application to remove all aquatic use sites, provide the data, or cite other data available to EPA, including certification of an offer to pay to rely on other data. Please see below for clarification:

Salt water marshes, irrigated cropland, rice fields, etc - your label contains several use sites which support aquatic non/food crop use patterns. Wildlife and aquatic organisms data requirements must be addressed. It is the Agency's understanding that you anticipate submission of data which may support these use sites. However, at this time, and until Agency receipt and approving review of such data, the above referenced use sites are unacceptable on the product label.

Please note that labeling comments are subject to change per review of requested materials.

75318-U End use product briquet for aquatic & food crop use sites

Your application for the proposed end use product B2E-05 proposes to rely (by formulator's exemption) on your pending MUP (75318-L) for which the core data deficiencies listed above need to be addressed before a decision on the registration of this product can be made. The Agency does allow for bridging of toxicology and non-target organism data when the studies are conducted on the test material of higher concentration than that of the concentration in the pending product and the additional inert ingredients are not likely to increase the potential for adverse effects or raise toxicological concerns. This method of data support (bridging from the source pending product) will be not acceptable in this case since this your proposed end use product varies substantially in inert composition from the source product. The submitted CSF lists certain inert ingredients (including a likely skin irritant), which alter the formulation such that the end-use product formulation cannot be considered similar enough to the source product (75318-L) to rely on its data with regards to toxicity and non-target organisms data requirements for registration applications. Therefore, pending approval of the source MUP, the following will be required at this time to support registration of this formulation:

1. ***Biochemical Pesticide Toxicity data***

You must submit product-specific data on your proposed end use product, or an acceptable waiver request which provides scientific rationale that justifies a waiver of each data requirement (40 CFR 158.690.) Because of the presence of a likely skin irritant in the formulation of this proposed product, the Agency expects that a dermal irritation and an acute dermal toxicity study will be required, although you have the option of requesting a waiver. If the waivers for these data are unacceptable, the guideline studies will have to be conducted on your formulated product, submitted for review and determined to be acceptable before the Agency can make a decision on your application.

2. ***Confidential Statement of Formula (CSF) deficiencies:***

a. [REDACTED]



██████████. In order to correctly identify the actual composition of the ██████████  
██████████ please list all three of these ingredients, their CAS numbers, and their percentage  
in the composition in the same box (box 10).

- b. The CAS# listed for the ██████████ on the CSF is incorrect, as it currently reflects the  
CAS # for ██████████. Please revise.

3. **Product Chemistry Data:**

Please clarify the statement, "Adjust the B2E-06 to obtain 40% active ingredient, if  
necessary." (found on page three of MRID 46115103 entitled "Description of the  
Formulation Process"). Based on the label and data for the MUP, the concentration of the  
active ingredient in the MUP should remain at 40% (B2E-06) without the need for  
adjustment.

4. **Product Performance Data:**

The submitted study MRID 461151-06 exhibits that B2E-05 was effective in controlling  
tested pests for 23 days. Based on the 95% minimum population reduction required in  
OPPTS guideline 810.3400, the data derived from the submitted studies do not support  
lasting efficacy of the product for 30 and 150 days as claimed on the product label. You  
must either amend your label to reflect the efficacious period exhibited in the study, or re-  
submit data which support the label claims.

5. **Product Label Review:** (refer to enclosed annotated label)

- a. Please indicate the net content/ weight of the product.
- b. Please provide the appropriate Establishment Number on the product label.
- c. It is preferred by the Agency that the Storage & Disposal section be displayed in boxed  
format, so that it can be easily distinguishable from other labeling language.
- d. Please incorporate the phrase, "To the fullest extent permitted by law," to your warranty  
statement, as it currently includes overly broad language regarding the limitations of  
liability.
- e. In the final paragraph under the heading "Application Rates," following the final sentence  
of the paragraph, please clarify on the label what is meant by the term "biological  
inspection," as this product also includes Residential use labeling language.
- f. Please revise the Directions for Use per PR Notice 2000-5, regarding mandatory and  
advisory statements. Also, please note other grammatical, typographical and punctuation  
comments on draft label.  
(pages 2-4 and 6)
- g. In the final sentence under the heading, "Introduction," please revise the final sentence to  
read:  
"B2E-05 prevents the emergence of adult *Culex* mosquitoes, which are known  
vectors of diseases, and may transmit West Nile Virus."



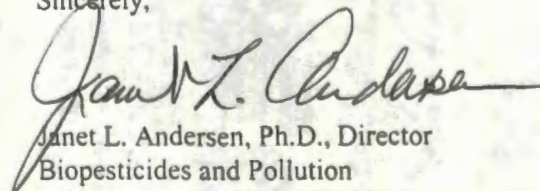
- h. Certain sites as listed on your proposed product label are not supported by the data you submitted. You must either provide the data or cite other data available to EPA, including certification of an offer to pay to rely on other data. Please see below for clarification:

Salt water marshes, irrigated cropland, rice fields, etc - your label contains several use sites which support aquatic non/food crop use patterns. Wildlife and aquatic organisms data requirements must be addressed. It is the Agency's understanding that you anticipate submission of data which may support these use sites. However at this time, and until Agency receipt and approving review of such data, the above referenced use sites are unacceptable on the product label.

Please note that labeling comments are subject to change per review of requested materials.

Your applications, as submitted under the Pesticide Registration Improvement Act (PRIA), have a decision date of 29 December 2004. With the deficiencies listed above, we cannot approve your applications. Please supply the missing guideline studies or data waiver requests with scientific rationales, correct the CSFs and labels as described above, clarify the product chemistry and product performance data, and if you so desire, remove unacceptable use sites from your label within 7 days. If you cannot address these deficiencies within this time frame, please contact Mari Duggard (703-308-0028, [duggard.mari@epa.gov](mailto:duggard.mari@epa.gov)) or me. We are willing to negotiate your due dates and may need to negotiate because the data and/or waiver requests will require more time to review than is remaining before the PRIA date. If we do not receive the data or waiver requests and the revised CSFs and labels, EPA will issue a notice that we cannot grant the registrations on or about December 28, 2004. If you wish to negotiate your due dates, please contact me directly. You are best advised to address each of your submissions separately for your resubmission so it is more clear to the front end processing unit how to properly route your data. We can negotiate new due dates for each action, or for the set of actions all at once.

Sincerely,

  
Janet L. Andersen, Ph.D., Director  
Biopesticides and Pollution  
Prevention Division (7511C)

Enclosures: copy of draft labels with comments  
Data Evaluation Records for submitted studies



# B2E Biotech LLC

500 Mamaroneck Ave. • Suite 201 • Harrison, NY 10528 • USA • Phone: 914-777-1111 • Fax: 914-777-0781  
• www.b2ecorp.com •

BY Fed Ex  
October 26, 2004

ATTN: Sheryl Reilly, Chief  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511W)  
U.S. Environmental Protection Agency  
1801 South Bell Street  
Arlington, VA 22202-4501

**EPA File Symbol: 75318-A**  
**Product Name: B2E-01**  
**Company Name: B2E Biotech LLC**

**Subject(s): Submission of a revised label in support of a pending application**

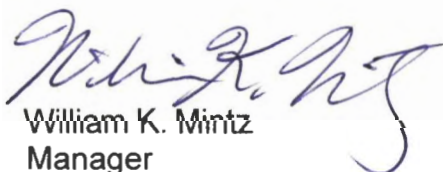
Dear Dr. Reilly:

Enclosed are five (5) copies of a revised label in support of our pending application referenced above. This label has been revised to accomplish the following:

1. Correct instructions in the First Aid section;
2. Correct application directions for compliance with PR Notice 2000-5;
3. Revise application directions for better readability;
4. Add sunflowers to Stored Products label;
5. Increase application rates on all crops related to Stored Products;
6. Revise Mixing & Handling instructions for better readability;
7. Change Midge and Filter Fly label application rate from 3-5 oz per million gallons flow to 3 oz per million gallons flow;
8. Add the following sites to the Mosquito label: grassy swales and floodplains; AND,
9. Add identifying footers.

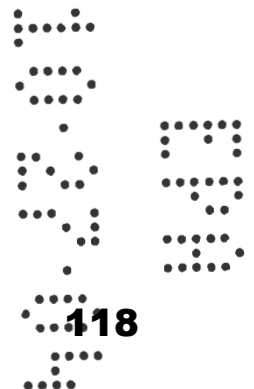
Should there be any questions, I can be contacted directly by phone at 631-537-9797 or by email (bmintz@b2ecorp.com). Thank you in advance for your consideration.

Sincerely,

  
William K. Mintz  
Manager

Enclosures

Rec'd  
OCT 28 2004  
BPPD





From: Origin ID: (914)777-1111  
B2E CORPORATION

500 MAMARONECK AVENUE  
SUITE 201  
HARRISON, NY 10528

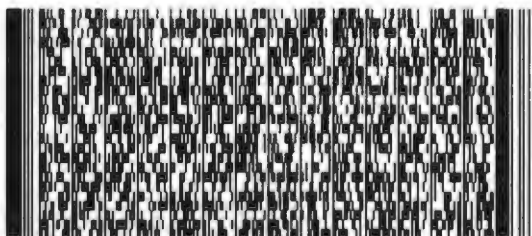


CL80014040506

SHIP TO: (703)308-8543

BILL SENDER

Dr. Gail Tomimatsu  
U.S. EPA - BPPD (7504C)  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 222024501



Ship Date: 26OCT04  
Actual Wgt: 1 LB  
System#: 4959108/INET2000  
Account#: S \*\*\*\*\*

REF: B2E-01 label 18F



Delivery Address Bar Code

STANDARD OVERNIGHT

WED

TRK# 7927 6283 9889

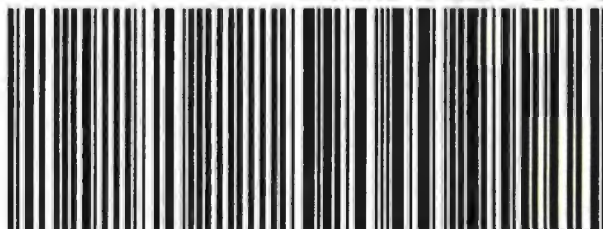
FORM  
0201Deliver By:  
27OCT04

IAD

A1

22202 -VA-US

ZM NDVA

**Shipping Label: Your shipment is complete**

1. Use the 'Print' feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

**Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.**

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.



**B2E-01  
MASTER LABEL**

**An Insect Growth Regulator**

*(to control insect pests in tobacco processing and storage facilities)  
(to prevent emergence of adult Sciarid flies in mushroom culture)  
(to prevent the emergence of stored product insects)  
(to prevent the emergence of adult filter flies & non-biting midges)  
(to prevent the emergence of adult floodwater mosquitoes)*

**ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #65733-16-6)..... 33.6%  
OTHER INGREDIENTS:..... 66.4%  
Total:..... 100.0%

EPA Reg No. 75318-  
EPA Est. No.

B2E Biotech LLC  
500 Mamaroneck Avenue  
Harrison, NY 10528

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**See (back panel) (side panel) (insert label) for additional precautionary statements**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

**FIRST AID**

<b>If in eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If on skin</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If swallowed</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor for treatment advice</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give any liquid to the person.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-XXX-XXX-XXXX for emergency medical treatment information.



## ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of rinsate or equipment washwaters.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### PESTICIDE STORAGE

Store in a cool, dry place.

### PESTICIDE DISPOSAL

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. Do not reuse container.

## WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Always read the label before using this product.

For information, call 1-XXX-XXX-XXXX or visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

## ***(Directions for Use for B2E-01 to control insect pests in tobacco processing and storage facilities)***

## **FOR PROTECTION OF STORED TOBACCO FROM DAMAGE BY CIGARETTE BEETLE (*LASIODERMA SERRICORNE*) AND TOBACCO MOTH (*EPHESTIA ELUTELLA*)**

### INTRODUCTION

B2E-01 is an emulsifiable concentrate formulation of the insect growth regulator, (S)-Methoprene. It is designed for use as a space spray in cold aerosol generators and in liquid concentrate form as an aqueous emulsified spray. Unlike traditional pesticides, (S)-Methoprene does not immediately kill immature insects; instead, it interferes with the normal insect development process and prevents adult pest emergence. B2E-01, prevents the adult emergence and reproduction of the Cigarette beetle (*Lasioderma serricorne*) and Tobacco moth (*Ephestia elutella*) when used according to label directions.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

#### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment that will achieve uniform dispersal for best treatment results.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for a minimum of 30 minutes (longer if possible) to allow the fine spray mist to settle. Do not remain in treated areas after treating. Ventilate treated areas before reentry. Repeat application as required.

#### APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Repeat application as required.



## MIXING INSTRUCTIONS

Partially fill clean application tank with water, add the specified amount of B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## *(Directions for Use for B2E-01 to prevent emergence of adult sciarid flies in mushroom culture)*

## AN INSECT GROWTH REGULATOR TO PREVENT THE EMERGENCE OF ADULT SCIARID FLIES IN MUSHROOM CULTURE

(WPS Language to be included in the Precautionary Statements)

### Personal Protection Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. For more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber (≥14 mils), barrier laminate, or viton (≥14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### Engineering Control Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)]. The handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

### User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## INTRODUCTION

S-Methoprene, the active ingredient in B2E-01 insect growth regulator (IGR), is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of S-Methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. B2E-01 prevents the emergence of adult Sciarid flies from the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adult flies present at the time of application will not be affected. If high adult fly populations are present, an initial use of a conventional adulticide will insure the best overall results. After treatment with B2E-01, larvae will continue to develop to the pupal stage where they will die. As B2E-01 prevents adult fly emergence, adult fly populations will be reduced over time. As maximum control is achieved two weeks after treatment, control assessment should be made at this time for most accurate evaluation.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.



### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses on this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: if the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber, (≥14 mils), barrier laminated, or viton (≥14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.

### METHOD, RATE, AND TIMING OF APPLICATION

Use either METHOD A, METHOD B, METHOD C, METHOD D or METHOD E

#### APPLICATION INSTRUCTIONS:

##### A. INCORPORATE AT TIME OF CASING

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft. Make spray application evenly, and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface immediately after placement.

##### B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING WHEN CASING LAYER IS PLACED ON COMPOST

###### In Compost:

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution. Spray on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

###### In Casing:

Mix B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

##### C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a spawn run longer than 15 days, a split application can be used.

###### First Application, On Compost:

Apply B2E-01 12 to 13 days after spawning. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

###### Second Application, In Casing:

Apply B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

##### D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS

###### First Application, In Casing:

Apply B2E-01 at the rate of 5½ fl. oz. per 1,000 sq. ft. in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

###### Second Application, On casing surface just prior to break:

Apply B2E-01 at the rate of 2¼ fl. oz. of per 1,000 sq. ft. in adequate water for even distribution as a surface drench prior to first break of mushrooms.



#### **E. DELAYED CASING SURFACE DRENCH**

##### **Surface drench 7 days after casing:**

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

##### **Surface drench 7 days and 14 days after casing:**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application on Casing:**

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.

##### **Second Application on Casing:**

Apply B2E-01 14 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### **MIXING AND HANDLING INSTRUCTIONS**

Partially fill clean application tank with water, add the specified amount of B2E-01, mix, and complete filling with water. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

#### **EFFECT ON MUSHROOMS**

In most cases, treatment with B2E-01 has a beneficial effect on mushroom yield by reducing Sciarid fly larval damage. As mushroom production practices differ among growers, the user can conduct small plots treatments to verify that reduced crop yields will not occur under cultural conditions used.

#### **(Directions for Use for B2E-01 to prevent the emergence of stored product insects)**

#### **AN INSECT GROWTH REGULATOR TO CONTROL STORED PRODUCT INSECTS IN STORED FOOD COMMODITIES, SUCH AS CEREAL GRAINS, GRAIN SORGHUM (MILO), CORN, POPCORN, BIRDSEED, PEANUTS, SUNFLOWER SEEDS & TO CONTROL INSECT PESTS IN SEEDS**

#### **INTRODUCTION**

(S)-Methoprene, the active ingredient in B2E-01, protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, B2E-01 is not an adulticide, but its residual activity prevents the development of larvae from developing into adults. B2E-01, when used according to the label directions, prevents regeneration of these and other insect pests: Almond Moth (*Ephestia cautella*), Indian Meal Moth (*Plodia interpunctella*), Cigarette Beetle (*Lasioderma serricorne*), Lesser Grain Beetle (*Rhyzopertha dominica*), Sawtooth Grain Beetle (*Oryzaephilus surinamensis*), Merchant Grain Beetle (*Oryzaephilus mercator*), Red Flour Beetle (*Tribolium castaneum*), and Confused Flour Beetle (*Tribolium confusum*). Treat existing insect populations with an adulticide before applying B2E-01 for residual protection.

Apply B2E-01 to any food commodity (including but not limited to: cereal grains, corn, sunflower, canola, popcorn, wheat, spices, sorghum, rice, cocoa, peanuts, oats, and millet) for control of insect larvae. Use B2E-01 to treat pet food, animal feedstuffs, birdseed, and cotton hulls. B2E-01 can be applied to seed stock. Treated commodities can be processed within 24 hours following application.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

**Stored Commodities:** For protection of stored food, grains, animal feed, seeds used for oil and seed stock against stored product insects – for optimum results, thoroughly clean and treat storage areas prior to storing commodities. Apply B2E-01 to a top-dressing to stored products that have already been placed into bins or storage areas. For top-dressing applications, spray or fog the bin headspace paying particular attention to the top on the commodity mass, beams, ceilings, and rafters. Thorough coverage is essential. For surface treatments, apply 1 ml (1/30 oz.) of B2E-01 per 1000 square feet; or for space spray, apply 3 ml (1/10 oz.) per 10,000 cubic feet in sufficient water to provide adequate coverage. Do not flood top-dress area.



## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED:** Dilute B2E-01 with water and apply to the moving grain stream as a uniform coarse spray. Final water dilution volume is 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. Lower volumes of diluent can be used but, it is important to assure that the commodity mass is uniformly treated. Agitate water dilution during application.

A range of rates for different commodities is provided for flexibility during varying storage periods and conditions. For maximum residual, use higher rates; the lowest application rate offers shorter residual for commodities stored  $\leq 6$  months.

Apply B2E-01 in solution in accordance with the general directions, to stored products at the following rates per 1,000 bushels:

	<u>fl oz</u>	<u>ml</u>	<u>fl oz</u>	<u>ml</u>	<u>fl oz</u>	<u>ml</u>
Wheat	14.0	420	7.0	210	1.75	52
Corn	14.0	420	7.0	210	1.75	52
Sorghum (Milo)	14.0	420	7.0	210	1.75	52
Barley	12.0	360	6.0	180	1.50	45
Rice	12.0	360	6.0	180	1.50	45
Oats	8.0	240	4.0	120	1.0	30
Peanuts	8.0	240	4.0	120	1.0	30
Sunflowers	8.0	240	4.0	120	1.0	30

For information on rates for other commodities, contact your distributor.

## USE NOTES:

- Apply B2E-01 grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Partially fill clean application tank with water, add the specified amount of B2E-01, mix, and complete filling with specified quantity of water.
- Use diluted spray solution within 72 hours of mixing. Agitate before each use.
- Clean up extremely dusty sites prior to application.

Use B2E-01 as a fogging concentrate or surface spray for the treatment of stored product pests and other insect pests infesting warehouses, silos, storage bins, or other stored commodity areas. Apply B2E-01 in food processing, food service, food preparation, and food handling establishments including mills, bakeries, restaurants, taverns, industrial buildings, breweries, candy processing, pet food production, grocery stores, modes of transportation (rail cars, ships, and trucks), cereal processing and bottling facilities. Apply B2E-01 to packaged, canned, and bottled foodstuffs, as well as boxes, liners, and pallets. For application of B2E-01 as a fogging space spray, use the following directions.

### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment. Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

### APPLICATION WITH AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml (1/30 oz) per 1000 square feet of surface area or 3 ml (1/10 oz.) per 10,000 cubic feet. Use appropriate spray equipment to achieve uniform coverage.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave room closed for 30 minutes to allow spray mist to settle. Do not remain in the treated areas and ventilate before re-entry. Repeat application as required.



#### **APPLICATION AS AN AQUEOUS SPRAY**

To prepare a diluted spray solution, partially fill the mixing container with water, add 1 ml (1/30 oz) of B2E-01, mix and complete filling with a total of 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with a low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

When tank mixing B2E-01 with conventional aqueous adulticides, the more stringent label will apply. B2E-01 can also be used or mixed with diatomaceous earth.

#### **(Directions for Use for B2E-01 to prevent the emergence of adult filter flies & non-biting midges)**

### **PREVENTS THE EMERGENCE OF ADULT FILTER FLIES AND MIDGES - KEEPS INFESTATIONS UNDER CONTROL**

#### **INTRODUCTION**

B2E-01 is a unique emulsifiable concentrate formulation that controls filter flies (*Psychodidae*), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. B2E-01 contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. B2E-01 does not control adults but prevents the larval stage from developing into flying adults. B2E-01 keeps pest infestations under control by stopping the reproduction cycle, without shutting down your treatment facility. Regular use of B2E-01 prevents these pests from developing into annoying infestations.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **APPLICATION DIRECTIONS**

##### **WASTE WATER TREATMENT FACILITY PESTS**

Use B2E-01 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

##### **WHAT TO EXPECT IN CONTINUOUS FLOW WASTE WATER TREATMENT FACILITIES**

To achieve effective results, B2E-01 must be applied to continuous flow systems on a daily basis for 10 days. A gradual reduction in the number of adult pests will be seen over a 7 day period with significant reduction seen after 14 days of treatment. Failure to apply B2E-01 daily may produce erratic results. Very heavy infestations often require slightly longer to achieve the desired control level. Since the mode of action of B2E-01 is to prevent adult emergence, pupa and adults present at the time of initial application will complete their life cycle. Pest populations can be expected to rebound within 2-3 weeks following the last day of treatment.

##### **SLUDGE OR SOLID WASTE APPLICATIONS**

For sludge solid waste applications, use 3 ounces per million gallons of sludge or solids. Apply dilution until the drying beds have been filled, then stop the application. Make applications at the influent side as the sludge or solids enter into the drying beds. Application of B2E-01 to solids will prevent pest insect emergence and keep infestations under control.

#### **APPLICATION METHODS**

##### **WASTE WATER TREATMENT FACILITIES**

Dilute B2E-01 with water prior to use. Apply B2E-01 by use of a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence product dilution. Prepare the desired volume of dilution to apply over a 6-8 hour period, or in cases of sludge drying beds, apply until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of B2E-01 over a 6-8 hour period.



## APPLICATION RATES

### WASTE WATER TREATMENT PESTS

To control waste water pests, apply 3 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply at the influent side over a 6-8 hour period during the lowest flow period of the day. For best results, make the application on a daily basis for 10 days or until suppression of pests is achieved.

### APPLICATION TO WASTE WATER – TRICKLING FILTER

Apply 3 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply the material. Apply at times of low flow periods (typically evening through early morning hours) for 6-8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 10 days or until suppression of pests is achieved.

## MIXING AND HANDLING INSTRUCTIONS:

Partially fill clean application tank with water, add the specified amount of B2E-01, mix, and complete filling with water. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## APPLICATION SITES

### WASTE WATER TREATMENT FACILITIES

Make applications of B2E-01 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem. Make B2E-01 applications as the sewage enters (influent areas) the waste water treatment area. For best results, apply to the influent side.

***(Directions for Use for B2E-01 to prevent the emergence of adult floodwater mosquitoes)***

## PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES

### INTRODUCTION

B2E-01 provides effective levels of S-Methoprene insect growth regulator to prevent the emergence of adult floodwater mosquitoes from treated water. B2E-01 can be applied either diluted in water or used to make granules. Treated larvae continue to develop normally to the pupal stage where they die. B2E-01 prevents the emergence of adult floodwater mosquitoes (*Aedes*, *Ochlerotatus* and *Psorophora*) from treated water.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### APPLICATION DIRECTIONS

Apply B2E-01 to 4th instar floodwater mosquito larvae prior to pupation to prevent adult emergence. Apply B2E-01 in the late afternoon or evening to extend the effective control window. Proper treatment timing is important for best results. For ground and aerial application, use the amount of B2E-01 listed below in sufficient water to give complete coverage. Do not apply when weather conditions will cause drift from the areas to be treated. Use B2E-01 granules to make treatments under windy conditions or to dense vegetation.

**NOTE:** The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

### APPLICATION RATES

Apply 0.5 ounce to 1.5 ounces (15 to 44 ml) of B2E-01 per acre in water. Within this range, use lower rates when applying to shallow water (<2 foot deep) and vegetation is minimal. Use higher application rates when water is deep (>2 foot deep) and vegetation is heavy, or when application conditions require treatments to be made earlier in larval development than recommended. Application of B2E-01 to sites subject to water flow or exchange will diminish the product's effectiveness and requires higher application rates and/or more frequent applications.



## MIXING AND HANDLING INSTRUCTIONS

Partially fill clean application tank with water, add the specified amount of **B2E-01**, mix, and complete filling with water. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## APPLICATION SITES

Apply **B2E-01** as directed above to floodwater habitats which support mosquito larval development. Examples of typical sites are: freshwater and salt water marshes, woodland pools and meadows, grassy swales, floodplains, irrigated croplands, pastures and rangeland (without removal of livestock), vineyards, rice fields (including wild rice), fruit and nut orchards, berry fields and bogs, and other natural and manmade depressions where mosquitoes may breed. In dense vegetation or canopy areas, use **B2E-01** to make granules on sand or other carrier following preparation instructions detailed below. Apply **B2E-01** Granules using standard granular dispersal equipment.

## B2E-01 GRANULES:

Granules can be made using washed, dry sand or other carriers. Apply **B2E-01** to the granule quantity to be applied per acre. For example, to apply 1.0 fl. oz./acre dosage rate on 5 pounds of granules per acre: Add 98 pounds of washed dry sand into a small rotary cement mixer. Tilt mixer to an angle 20° above horizontal. Measure out 20 fl. oz. of **B2E-01**, and add to a sprayer equipped with a flat fan nozzle. Pressurize sprayer and turn on mixer. Spray **B2E-01** on the rolling face of the sand until it is evenly dampened. Mix for 2 minutes, then add a drying agent (Microcel E or Hisil 233) as needed, to achieve a dry, free flowing granule. Discharge granules and bag. Apply within 72 hours.

Refer to table below for the number of ounces used to make 100 pound batches of granules applied at different rates per acre.

Dosage Rate Oz./Acre	Granule Application Rate/Acre (Lbs.)	Ounces of B2E-01 applied to granules
0.5	2.5	20
0.5	5.0	10
0.5	10.0	5
1.0	2.5	40
1.0	5.0	20
1.0	10.0	10
1.5	2.5	60
1.5	5.0	30
1.5	10.0	15



Draft

**B2E-01  
MASTER LABEL**

**An Insect Growth Regulator**

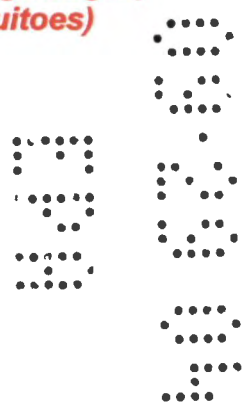
*(to control insect pests in tobacco processing and storage facilities)  
(to prevent emergence of adult Sciarid flies in mushroom culture)  
(to prevent the emergence of stored product insects)  
(to prevent the emergence of adult filter flies & non-biting midges)  
(to prevent the emergence of adult floodwater mosquitoes)*

**ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #65733-16-6)..... 33.6%  
OTHER INGREDIENTS:..... 66.4%  
Total:..... 100.0%

EPA Reg No. **75318-**  
EPA Est. No.           

B2E Biotech LLC  
500 Mamaroneck Avenue  
Harrison, NY 10528



**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**  
**See (back panel) (side panel) (insert label) for additional precautionary statements**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION**

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID	
If in eyes	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
If on skin	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
If swallowed	<ul style="list-style-type: none"><li>• Call a poison control center or doctor for treatment advice</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give any liquid to the person.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-XXX-XXX-XXXX for emergency medical treatment information.	



## ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of rinsate or equipment washwaters.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### PESTICIDE STORAGE

Store in a cool, dry place.

### PESTICIDE DISPOSAL

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. Do not reuse container.

## WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

*To the extent permitted by law,*  
Always read the label before using this product.

For information, call 1-XXX-XXX-XXXX or visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

***(Directions for Use for B2E-01 to control insect pests in tobacco processing and storage facilities)***

## FOR PROTECTION OF STORED TOBACCO FROM DAMAGE BY CIGARETTE BEETLE (*LASIODERMA SERRICORNE*) AND TOBACCO MOTH (*EPEHESTIA ELUTELLA*)

### INTRODUCTION

B2E-01 is a water based emulsifiable formulation of the insect growth regulator, (S)-Methoprene. It is designed for use as a space spray in cold aerosol generators and in liquid concentrate form as an aqueous emulsified spray. Unlike traditional pesticides, (S)-Methoprene does not immediately kill immature insects; instead, it interferes with the normal insect development process and prevents adult pest emergence. B2E-01, prevents the adult emergence and reproduction of the Cigarette beetle (*Lasioderma serricorne*) and Tobacco moth (*Ephestia elutella*) when used according to label directions.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

#### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment that will achieve uniform dispersal for best treatment results.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for a minimum of 30 minutes (longer if possible) to allow the fine spray mist to settle. Do not remain in treated areas after treating. Ventilate treated areas before reentry. Repeat application as required.

#### APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Repeat application as required.



## MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

## *(Directions for Use for B2E-01 to prevent emergence of adult sciarid flies in mushroom culture)*

## AN INSECT GROWTH REGULATOR TO PREVENT THE EMERGENCE OF ADULT SCIARID FLIES IN MUSHROOM CULTURE

(WPS Language to be included in the Precautionary Statements)

### Personal Protection Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. For more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber (≥14 mils), barrier laminate, or viton (≥14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### Engineering Control Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)]. The handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

### User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## INTRODUCTION

S-Methoprene, the active ingredient in B2E-01 insect growth regulator (IGR), is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of S-Methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. B2E-01 prevents the emergence of adult Sciarid flies from the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adult flies present at the time of application will not be affected. If high adult fly populations are present, an initial use of a conventional adulticide will insure the best overall results. After treatment with B2E-01, larvae will continue to develop to the pupal stage where they will die. As B2E-01 prevents adult fly emergence, adult fly *conduct* populations will be reduced over time. As maximum control is achieved two weeks after treatment, control assessment ~~should be made at this time~~ for most accurate evaluation.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.



*to workers*

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses on this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: if the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber, (≥14 mils), barrier laminated, or viton (≥14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.

### METHOD, RATE, AND TIMING OF APPLICATION

Use either METHOD A, METHOD B, METHOD C, METHOD D or METHOD E

#### APPLICATION INSTRUCTIONS:

##### A. INCORPORATE AT TIME OF CASING

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft. Make spray application evenly, and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface immediately after placement.

##### B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING WHEN CASING LAYER IS PLACED ON COMPOST

###### In Compost:

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution. Spray on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

###### In Casing:

Mix B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

##### C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a spawn run longer than 15 days, a split application can be used.

###### First Application, On Compost:

Apply B2E-01 12 to 13 days after spawning. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

###### Second Application, In Casing:

Apply B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

##### D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS

###### First Application, In Casing:

Apply B2E-01 at the rate of 5½ fl. oz. per 1,000 sq. ft. in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

###### Second Application, On casing surface just prior to break:

Apply B2E-01 at the rate of 2¼ fl. oz. of per 1,000 sq. ft. in adequate water for even distribution as a surface drench prior to first break of mushrooms.



#### E. DELAYED CASING SURFACE DRENCH

Surface drench 7 days after casing:

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

Surface drench 7 days and 14 days after casing:

For those crops that have a spawn run longer than 15 days, a split application can be used.

First Application on Casing:

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.

Second Application on Casing:

Apply B2E-01 14 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### MIXING AND HANDLING INSTRUCTIONS

1. Shake container before using.
2. Add the measured amount of B2E-01 to a spray tank partially filled with water, mix, and complete filling with the remaining water.
3. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

#### EFFECT ON MUSHROOMS

In most cases, treatment with B2E-01 has a beneficial effect on mushroom yield by reducing Sciarid fly larval damage. As mushroom production practices differ among growers, the user can conduct small plots treatments to verify that reduced crop yields will not occur under cultural conditions used.

**(Directions for Use for B2E-01 to prevent the emergence of stored product insects)**

#### AN INSECT GROWTH REGULATOR TO CONTROL STORED PRODUCT INSECTS IN STORED FOOD COMMODITIES, SUCH AS CEREAL GRAINS, GRAIN SORGHUM (MILO), CORN, POPCORN, BIRDSEED, PEANUTS, SUNFLOWER SEEDS & TO CONTROL INSECT PESTS IN SEEDS

#### INTRODUCTION

(S)-Methoprene, the active ingredient in B2E-01, protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, B2E-01 is not an adulticide, but its residual activity prevents the development of larvae from developing into adults. B2E-01, when used according to the label directions, prevents regeneration of these and other insect pests: Almond Moth (*Ephestia cautella*), Indian Meal Moth (*Plodia interpunctella*), Cigarette Beetle (*Lasioderma serricorne*), Lesser Grain Beetle (*Rhyzopertha dominica*), Sawtooth Grain Beetle (*Oryzaephilus surinamensis*), Merchant Grain Beetle (*Oryzaephilus mercator*), Red Flour Beetle (*Tribolium castaneum*), and Confused Flour Beetle (*Tribolium confusum*). Treat existing insect populations with an adulticide before applying B2E-01 for residual protection.

Apply B2E-01 to any food commodity (including but not limited to: cereal grains, corn, sunflower, canola, popcorn, wheat, spices, sorghum, rice, cocoa, peanuts, oats, and millet) for control of insect larvae. Use B2E-01 to treat pet food, animal feedstuffs, birdseed, and cotton hulls. B2E-01 can be applied to seed stock. Treated commodities can be processed within 24 hours following application.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

**Stored Commodities:** For protection of stored food, grains, animal feed, seeds used for oil and seed stock against stored product insects – for optimum results, thoroughly clean and treat storage areas prior to storing commodities. Apply B2E-01 to a top-dressing to stored products that have already been placed into bins or storage areas. For top-dressing applications, spray or fog the bin headspace paying particular attention to the top on the commodity mass, beams, ceilings, and rafters. Thorough coverage is essential. For surface treatments, apply 1 ml (1/30 oz.) of B2E-01 per 1000 square feet; or for space spray, apply 3 ml (1/10 oz.) per 10,000 cubic feet in sufficient water to provide adequate coverage. Do not flood top-dress area.



## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED:** Dilute B2E-01 with water and apply to the moving grain stream as a uniform coarse spray. Final water dilution volume is 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. Lower volumes of diluent can be used but, it is important to assure that the commodity mass is uniformly treated. Agitate water dilution during application.

A range of rates for different commodities is provided for flexibility during varying storage periods and conditions. For maximum residual, use higher rates; the lowest application rate offers shorter residual for commodities stored  $\leq 6$  months.

Apply B2E-01 in solution in accordance with the general directions, to stored products at the following rates per 1,000 bushels:

	<u>fl oz</u>	<u>ml</u>	<u>fl oz</u>	<u>ml</u>	<u>fl oz</u>	<u>ml</u>
Wheat	14.0	420	7.0	210	1.75	52
Corn	14.0	420	7.0	210	1.75	52
Sorghum (Milo)	14.0	420	7.0	210	1.75	52
Barley	12.0	360	6.0	180	1.50	45
Rice	12.0	360	6.0	180	1.50	45
Oats	8.0	240	4.0	120	1.0	30
Peanuts	8.0	240	4.0	120	1.0	30
Sunflowers	8.0	240	4.0	120	1.0	30

For information on rates for other commodities, contact your distributor.

## USE NOTES:

- Apply B2E-01 grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of B2E-01 to a spray tank partially filled with water, mix, and complete filling with specified quantity of water.
- Use diluted spray solution within 72 hours of mixing. Agitate before each use.
- Clean up extremely dusty sites prior to application.

Use B2E-01 as a fogging concentrate or surface spray for the treatment of stored product pests and other insect pests infesting warehouses, silos, storage bins, or other stored commodity areas. Apply B2E-01 in food processing, food service, food preparation, and food handling establishments including mills, bakeries, restaurants, taverns, industrial buildings, breweries, candy processing, pet food production, grocery stores, modes of transportation (rail cars, ships, and trucks), cereal processing and bottling facilities. Apply B2E-01 to packaged, canned, and bottled foodstuffs, as well as boxes, liners, and pallets. For application of B2E-01 as a fogging space spray, use the following directions.

### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment. Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

### APPLICATION WITH AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml (1/30 oz) per 1000 square feet of surface area or 3 ml (1/10 oz.) per 10,000 cubic feet. Use appropriate spray equipment to achieve uniform coverage.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave room closed for 30 minutes to allow spray mist to settle. Do not remain in the treated areas and ventilate before re-entry. Repeat application as required.



#### APPLICATION AS AN AQUEOUS SPRAY

To prepare a diluted spray solution, partially fill the mixing container with water, add 1 ml (1/30 oz) of B2E-01, mix and complete filling with a total of 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with a low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

When tank mixing B2E-01 with conventional aqueous adulticides, the more stringent label will apply. B2E-01 can also be used or mixed with diatomaceous earth.

#### *(Directions for Use for B2E-01 to prevent the emergence of adult filter flies & non-biting midges)*

### PREVENTS THE EMERGENCE OF ADULT FILTER FLIES AND MIDGES - KEEPS INFESTATIONS UNDER CONTROL

#### INTRODUCTION

B2E-01 is a unique water based product that controls filter flies (*Psychodidae*), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. B2E-01 contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. B2E-01 does not control adults but prevents the larval stage from developing into flying adults. B2E-01 keeps pest infestations under control by stopping the reproduction cycle, without shutting down your treatment facility. Regular use of B2E-01 prevents these pests from developing into annoying infestations.

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### APPLICATION DIRECTIONS

##### WASTE WATER TREATMENT FACILITY PESTS

Use B2E-01 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

##### WHAT TO EXPECT IN CONTINUOUS FLOW WASTE WATER TREATMENT FACILITIES

To achieve effective results, B2E-01 must be applied to continuous flow systems on a daily basis for 10 days. A gradual reduction in the number of adult pests will be seen over a 7 day period with significant reduction seen after 14 days of treatment. Failure to apply B2E-01 daily may produce erratic results. Very heavy infestations often require slightly longer to achieve the desired control level. Since the mode of action of B2E-01 is to prevent adult emergence, pupa and adults present at the time of initial application will complete their life cycle. Pest populations can be expected to rebound within 2-3 weeks following the last day of treatment.

##### SLUDGE OR SOLID WASTE APPLICATIONS

For sludge solid waste applications, use 3 ounces per million gallons of sludge or solids. Apply dilution until the drying beds have been filled, then stop the application. Make applications at the influent side as the sludge or solids enter into the drying beds. Application of B2E-01 to solids will prevent pest insect emergence and keep infestations under control.

#### APPLICATION METHODS

##### WASTE WATER TREATMENT FACILITIES

*how much*  
Dilute B2E-01 with water prior to use. Apply B2E-01 by use of a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence product dilution. Prepare the desired volume of dilution to apply over a 6-8 hour period, or in cases of sludge drying beds, apply until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of B2E-01 over a 6-8 hour period.



## APPLICATION RATES

### WASTE WATER TREATMENT PESTS

To control waste water pests, apply 3 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply at the influent side over a 6-8 hour period during the lowest flow period of the day. For best results, make the application on a daily basis for 10 days or until suppression of pests is achieved.

### APPLICATION TO WASTE WATER – TRICKLING FILTER

Apply 3 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply the material. Apply at times of low flow periods (typically evening through early morning hours) for 6-8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 10 days or until suppression of pests is achieved.

## MIXING AND HANDLING INSTRUCTIONS:

Partially fill the application tank with water; then add the specified amount of B2E-01, agitate, and complete filling with water. Agitate mildly during application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

## APPLICATION SITES

### WASTE WATER TREATMENT FACILITIES

*Apply* Make applications of B2E-01 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem. Make B2E-01 applications as the sewage enters (influent areas) the waste water treatment area. For best results, apply to the influent side.

***(Directions for Use for B2E-01 to prevent the emergence of adult floodwater mosquitoes)***

## PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES

### INTRODUCTION

B2E-01 provides effective levels of S-Methoprene insect growth regulator to prevent the emergence of adult floodwater mosquitoes from treated water. B2E-01 can be applied either diluted in water or used to make granules. Treated larvae continue to develop normally to the pupal stage where they die. B2E-01 prevents the emergence of adult floodwater mosquitoes (*Aedes*, *Ochlerotatus* and *Psorophora*) from treated water.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### APPLICATION DIRECTIONS

Apply B2E-01 to 4th instar floodwater mosquito larvae prior to pupation to prevent adult emergence. Apply B2E-01 in the late afternoon or evening to extend the effective control window. Proper treatment timing is important for best results. For ground and aerial application, use the amount of B2E-01 listed below in sufficient water to give complete coverage. Do not apply when weather conditions will cause drift from the areas to be treated. Use B2E-01 granules to make treatments under windy conditions or to dense vegetation.

**NOTE:** The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

### APPLICATION RATES

Apply 0.5 ounce to 1.5 ounces (15 to 44 ml) of B2E-01 per acre in water. Within this range, use lower rates when applying to shallow water (<2 foot deep) and vegetation is minimal. Use higher application rates when water is deep (>2 foot deep) and vegetation is heavy, or when application conditions require treatments to be made earlier in larval development than recommended. Application of B2E-01 to sites subject to water flow or exchange will diminish the product's effectiveness and requires higher application rates and/or more frequent applications.



## MIXING AND HANDLING INSTRUCTIONS

1. B2E-01 is a water emulsifiable concentrate which requires agitation for uniform suspension. Separation occurs on standing, thus agitate prior to application.
2. Use clean equipment.
3. Partially fill spray tank with water; then add B2E-01, agitate and complete filling.
4. Use spray solutions within 48 hours; always agitate before and during spraying.

## APPLICATION SITES

Apply B2E-01 as directed above to floodwater habitats which support mosquito larval development. Examples of typical sites are: freshwater and salt water marshes, woodland pools and meadows, grassy swales, floodplains, irrigated croplands, pastures and rangeland (without removal of livestock), vineyards, rice fields (including wild rice), fruit and nut orchards, berry fields and bogs, and other natural and manmade depressions where mosquitoes may breed. In dense vegetation or canopy areas, use B2E-01 to make granules on sand or other carrier following preparation instructions detailed below. Apply B2E-01 Granules using standard granular dispersal equipment.

## B2E-01 GRANULES:

Granules can be made using washed, dry sand or other carriers. Apply B2E-01 to the granule quantity to be applied per acre. For example, to apply 1.0 fl. oz./acre dosage rate on 5 pounds of granules per acre: Add 98 pounds of washed dry sand into a small rotary cement mixer. Tilt mixer to an angle 20° above horizontal. Measure out 20 fl. oz. of B2E-01, and add to a sprayer equipped with a flat fan nozzle. Pressurize sprayer and turn on mixer. Spray B2E-01 on the rolling face of the sand until it is evenly dampened. Mix for 2 minutes, then add a drying agent (Microcel E or Hisil 233) as needed, to achieve a dry, free flowing granule. Discharge granules and bag. Apply within 72 hours.

Refer to table below for the number of ounces used to make 100 pound batches of granules applied at different rates per acre.

Dosage Rate Oz./Acre	Granule Application Rate/Acre (Lbs.)	Ounces of B2E-01 applied to granules
0.5	2.5	20
0.5	5.0	10
0.5	10.0	5
1.0	2.5	40
1.0	5.0	20
1.0	10.0	10
1.5	2.5	60
1.5	5.0	30
1.5	10.0	15





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

May 4, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

B2E BIOTECH LLC  
500 MAMARONECK AVENUE, SUITE 201  
HARRISON, NY 10528

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 18-MAR-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [06]:

\* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR 160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear on page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.



# Receipt for Section 3

S: 756385

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☐ Yes ☒ No

Company: 75318 B2E BIOTECH LLC ☒

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 75318-A Product Name: B2E-01

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 01-Mar-2004

OPP Rec'd Date: 18-Mar-2004

Front End Date: 18-Mar-2004

Risk Manager Send Date: 18-Mar-2004

Receipt Content  
Study

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

New Ingredient Request Date:   
New Ingredient Received Date:   
Signature Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:



# B2E Biotech LLC

500 Mamaroneck Ave. • Suite 201 • Harrison, NY 10528 • USA • Phone: 914-777-1111 • Fax: 914-777-0781  
• www.b2ecorp.com •

BY HAND

March 15, 2004

U.S. Environmental Protection Agency  
ATTN: Sherryl Reilly  
Biopesticides & Pollution Prevention Div. (7511W)  
401 M Street SW  
Washington, D.C. 20460

**EPA File #:** 75318-  
**Product Name:** B2E-01  
**Company Name:** B2E Biotech LLC

**Subject(s):** Application for Biochemical End Use Product

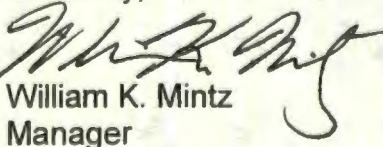
Dear Ms. Reilly:

Enclosed are three (3) volumes consisting of Administrative Materials [Volume 1], Product Chemistry [Volumes 2(A) through 2(D)] and Product Performance [Volumes 3(A) through 3(C)] for our new product application.

- **Please Note (1):** The Confidential Statement of Formula (CSF) is in the Confidential Attachment of Volume 2A – Product Identity and Composition.
- **Please Note (2):** The labeling for this product is a "Master Label". The label has been printed in color to help make the "sub" labeling discreet. Lettering in black is used on all labels. Individual colors are for each specific "sub" label.

Should there be any questions, I can be contacted directly by phone at 631-537-9797 or by email (bmintz@b2ecorp.com). Thank you in advance for your consideration.

Sincerely,

  
William K. Mintz  
Manager

Enclosures



## TRANSMITTAL DOCUMENT

1. Submitter:

B2E Biotech LLC  
500 Mamaroneck Ave.  
Harrison, NY 10528

2. Subject: Application for End Use Product B2E-01

3. Transmittal Date: March 16, 2004

4. List of Submitted Studies:

**Vol. 1** Administrative Materials – 40 CFR Subpart C

**Vol. 2** Product Chemistry

**46225401** Product Identity and Composition  
(OPPTS 830.1550) – **Vol. 2(A)**  
**46225402** Description of Materials Used to Produce the Product  
(OPPTS 830.1600) – **Vol. 2(B)**  
**46225403** Description of the Formulation Process  
(OPPTS 830.1620) – **Vol. 2(C)**  
**46225404** Certified Limits  
(OPPTS 830.1750) – **Vol. 2(D)**

**Vol. 3** Product Performance

**46225405** Bridging Data – Study No. B09-03-0013A  
(OPPTS 810.3400) – **Vol. 3(A)**  
**Reject (06)** Efficacy Data – Study No. 080403  
(OPPTS 810.3400) – **Vol. 3(B)**  
**46225407** Efficacy Data – Study No. DTG09-03-0013C  
(OPPTS 810.3400) – **Vol. 3(C)**

Company Official: William K. Mintz, Manager

Company: B2E Biotech LLC

Company Contact: William K. Mintz Phone #: 631-537-9797



## TRANSMITTAL DOCUMENT

1. Submitter:

B2E Biotech LLC  
500 Mamaroneck Ave.  
Harrison, NY 10528

2. Subject: Application for End Use Product B2E-01

3. Transmittal Date: March 16, 2004

4. List of Submitted Studies:

**Vol. 1** Administrative Materials – 40 CFR Subpart C

**Vol. 2** Product Chemistry

**46225401** Product Identity and Composition  
(OPPTS 830.1550) – **Vol. 2(A)**  
**46225402** Description of Materials Used to Produce the Product  
(OPPTS 830.1600) – **Vol. 2(B)**  
**46225403** Description of the Formulation Process  
(OPPTS 830.1620) – **Vol. 2(C)**  
**46225404** Certified Limits  
(OPPTS 830.1750) – **Vol. 2(D)**

**Vol. 3** Product Performance

**46225405** Bridging Data – Study No. B09-03-0013A  
(OPPTS 810.3400) – **Vol. 3(A)**  
**Reject (06)** Efficacy Data – Study No. 080403  
(OPPTS 810.3400) – **Vol. 3(B)**  
**46225407** Efficacy Data – Study No. DTG09-03-0013C  
(OPPTS 810.3400) – **Vol. 3(C)**

Company Official: William K. Mintz, Manager

Company: B2E Biotech LLC

Company Contact: William K. Mintz Phone #: 631-537-9797



## MEMORANDUM

DATE: 5 / 5 / 04

TO: BPPD, Regulatory Manager

FROM: Information Services Branch, IRSD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately two weeks from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Maureen Sherrill (305-5361) or Teresa Downs (305-5363).

This is a: ☐ fully accepted submission  
☒ partially accepted submission  
☐ rejected submission



NOTE TO FILE; 7-2-04

ALTHOUGH ~~THE~~ one  
study was rejected it  
~~it still~~ has been forwarded  
for review.

gt



# B2E Biotech LLC

500 Mamaroneck Ave. • Suite 201 • Harrison, NY 10528 • USA • Phone: 914-777-1111 • Fax: 914-777-0781  
• www.b2ecorp.com •

BY HAND

March 15, 2004

U.S. Environmental Protection Agency  
ATTN: Sherryl Reilly  
Biopesticides & Pollution Prevention Div. (7511W)  
401 M Street SW  
Washington, D.C. 20460

EPA File #: 75318-  
Product Name: B2E-01  
Company Name: B2E Biotech LLC

**Subject(s): Application for Biochemical End Use Product**

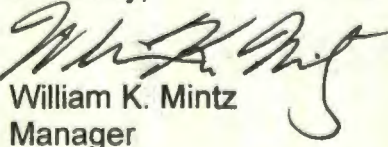
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Sincerely,

  
William K. Mintz  
Manager

Enclosures



## TRANSMITTAL DOCUMENT

1. Submitter:

B2E Biotech LLC  
500 Mamaroneck Ave.  
Harrison, NY 10528

2. Subject: Application for End Use Product B2E-01

3. Transmittal Date: March 16, 2004

4. List of Submitted Studies:

**Vol. 1** Administrative Materials – 40 CFR Subpart C

**Vol. 2** Product Chemistry

- 46225401** Product Identity and Composition  
(OPPTS 830.1550) – **Vol. 2(A)**
- 46225402** Description of Materials Used to Produce the Product  
(OPPTS 830.1600) – **Vol. 2(B)**
- 46225403** Description of the Formulation Process  
(OPPTS 830.1620) – **Vol. 2(C)**
- 46225404** Certified Limits  
(OPPTS 830.1750) – **Vol. 2(D)**

**Vol. 3** Product Performance

- 46225405** Bridging Data – Study No. B09-03-0013A  
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(OPPTS 810.3400) – **Vol. 3(B)**
- 46225407** Efficacy Data – Study No. DTG09-03-0013C  
(OPPTS 810.3400) – **Vol. 3(C)**

Company Official: William K. Mintz, Manager

Company: B2E Biotech LLC

Company Contact: William K. Mintz

Phone #: 631-537-9797



## NEW APPLICATIONS

DATE: 3/18/04

FILE NUMBER: 75318-A

FEP (OPPIN ENTRY) 3/18/04 *am*  
(Initial & date)

FILE ROOM: *LA* 3/19/04  
(Initial & date)

SIG: *KC 3/22/04*  
(Initial & date)

FILE ROOM: 3/23/04  
(Initial & date)

\_\_\_ ASSIGN TO PM \_\_\_ (NO DATA)

☒ JACKET TO SHELF (DATA)





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 18, 2004

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

WILLIAM K. MINTZ  
B2E BIOTECH LLC  
500 MAMARONECK AVENUE, SUITE 201  
HARRISON, NY 10528

PRODUCT NAME: B2E-01  
COMPANY NAME: B2E BIOTECH LLC  
EPA FILE SYMBOL: 75318-A  
EPA RECEIPT DATE: 03/18/04

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process and does NOT constitute approval.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-8269.

Sincerely,

*Patricia A. Moore*

Front End Processing Staff  
Information Services Branch  
Information Resources and Services Division





Read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number B2E Biotech LLC / 75318 - A	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted Biochemical
4. Company/Product (Name) B2E Biotech LLC / B2E-01	PM# 1120 91	
5. Name and Address of Applicant (Include ZIP Code) 500 Mamaroneck Avenue Suite 201 Harrison, New York 10528 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container None		5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name William K. Mintz		Title Manager		Telephone No. (Include Area Code) 631-537-9797	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
Signature 		3. Title Manager			
4. Typed Name William K. Mintz		5. Date March 1, 2004			



NYF/T

# B2E Biotech LLC

500 Mamaroneck Ave. • Suite 201 • Harrison, NY 10528 • USA • Phone: 914-777-1111 • Fax: 914-777-0781  
• www.b2ecorp.com •

BY HAND ✓

March 15, 2004

U.S. Environmental Protection Agency  
ATTN: Sherryl Reilly  
Biopesticides & Pollution Prevention Div. (7511W)  
401 M Street SW  
Washington, D.C. 20460

EPA File #: 75318-  
Product Name: B2E-01  
Company Name: B2E Biotech LLC

Subject(s): Application for Biochemical End Use Product

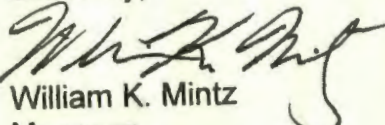
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Sincerely,

  
William K. Mintz  
Manager

Enclosures



Fax = 631-537-8695

# TRANSMITTAL DOCUMENT

1. Submitter:

B2E Biotech LLC  
500 Mamaroneck Ave.  
Harrison, NY 10528

2. Subject: Application for End Use Product B2E-01

3. Transmittal Date: March 16, 2004

4. List of Submitted Studies:

**Vol. 1** Administrative Materials – 40 CFR Subpart C

**Vol. 2** Product Chemistry

Product Identity and Composition  
(OPPTS 830.1550) – **Vol. 2(A)**

Description of Materials Used to Produce the Product  
(OPPTS 830.1600) – **Vol. 2(B)**

Description of the Formulation Process  
(OPPTS 830.1620) – **Vol. 2(C)**

Certified Limits  
(OPPTS 830.1750) – **Vol. 2(D)**

**Vol. 3** Product Performance

Bridging Data – Study No. B09-03-0013A  
(OPPTS 810.3400) – **Vol. 3(A)**

Efficacy Data – Study No. 080403

(OPPTS 810.3400) – **Vol. 3(B)**

Efficacy Data – Study No. DTG09-03-0013C  
(OPPTS 810.3400) – **Vol. 3(C)**

Company Official: William K. Mintz, Manager

Company: B2E Biotech LLC

Company Contact: William K. Mintz Phone #: 631-537-9797

Gails Fax is 703-305-0110

...

...

...

We do not have these  
#s.  
Just send to  
Fax  
Gail and  
she can pull  
blow back.



June 8-2004

Per Travello to A. Roberts / Bill Mintz

GLP- ~~the~~ statement not  
properly formatted in  
Vol. 3B.

said He faxed the page →  
to Travello.

---

Travello will check on.



# VOLUME 1

## TITLE

Administrative Materials  
Application for End Use Product  
B2E-01

## DATA REQUIREMENTS

40 CFR Subpart D 158.690(d)

## AUTHOR

William K. Mintz

## STUDY COMPLETED ON

March 1, 2004

## PERFORMING LABORATORY

N/A

## Study Number

B03-04-0011

## SUBMITTED BY

**B2E Biotech LLC  
500 Mamaroneck Ave.  
Harrison, NY 10528**





## STATEMENT OF DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA section 10(d)(1)(A), (B), or (C).

No supplemental claim of confidentiality is made for the information contained in these studies on the basis of FIFRA section 10(a) or (b). This document, however, is proprietary to B2E Biotech LLC and is considered to be confidential and trade secret information in all other countries and for all purposes other than those enunciated in FIFRA section 3 and section 10.

Information contained in these studies should not be reviewed, abstracted, or used by persons other than EPA without the expressed written consent of B2E Corporation, except as required to carry out the requirements of FIFRA.

Submitter: B2E Biotech LLC  
500 Mamaroneck  
Harrison, NY 10528

Company Agent: William K. Mintz

Date: March 1, 2004

Title: Manager

  
Signature



GLP COMPLIANCE STATEMENT

This study does not meet the requirements of 40 CFR Part 160, and differs in the following way:

This information is not subject to GLP standards.

Submitter: B2E Biotech LLC  
500 Mamaroneck  
Harrison, NY 10528

Company Agent: William K. Mintz

Date: March 1, 2004

Title: Manager

  
Signature



## TABLE OF CONTENTS

Confidentiality Claims.....	Page 2
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Data Matrix.....	Page 18
Certificates of Permission.....	Page 20





United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

**Applicant's Name and Address**

B2E BIOTECH LLC  
500 Mamaroneck Avenue  
Suite 201  
Harrison, New York 10528

**EPA File Symbol/Registration Number**

75318 -

**Product Name**

B2E-01

**Date of Confidential Statement of Formula (EPA Form 8570-4)**

September 2, 2003

As an authorized representative of the applicant for registration of the product identified above, I certify that:

**(1) This product contains the following active ingredient(s):**

(S)-Methoprene

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

**(3) Indicate by checking (A) or (B) below which paragraph applies:**

☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☒ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

**(4) The following active ingredients in this product qualify for the formulator's exemption.****Source**

Active Ingredient	Product Name	Registration Number
(S)-Methoprene	(S)-Methoprene Technical R-ST SM Insect Growth Regulator	74032-1
<b>Signature</b> 	<b>Name and Title</b> William K. Mintz, Manager	<b>Date</b> March 1, 2004





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number B2E BIOTECH LLC, 500 Mamaroneck Avenue Suite 201, Harrison, NY 10528	EPA Registration Number/File Symbol 75318-6
Active Ingredient(s) and/or representative test compound(s) (S)-Methoprene (S-Methoprene Technical R-ST SM Insect Growth Regulator)	Date March 1, 2004
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) End Use Product	Product Name B2E-01

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐

I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐

I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒

I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

3/1/04

Typed or Printed Name and Title

William K. Mintz, Manager





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1 hour per response for registration activities and 1 hour per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)**

1. PRODUCT NAME: B2E-01		2. Reg. No. 75318-
3. COMPANY NAME: B2E Biotech LLC		4. SUBMISSION DATE: March 1, 2004
5. FIRST SUBMISSION <input checked="" type="checkbox"/> 6. RESUBMISSION <input type="checkbox"/>	7. PESTICIDE TYPE: Biopesticide - Insect Growth Regulator	10. REGISTRATION <input checked="" type="checkbox"/>
8. FORMULATED MANUFACTURING-USE PRODUCT <input type="checkbox"/> or 9. END-USE PRODUCT <input checked="" type="checkbox"/>		11. REREGISTRATION <input type="checkbox"/>
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN): Sheryl Reilly PM 1120		12. REREG CASE #
14. GUIDELINE REFERENCE NO.(GRN)/TITLE	15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES	16. MRID or REPORT NO.

**Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)**

-6302	Color	white	001-004333/2
-6303	Physical State	liquid	001-004333/2
-6304	Odor	mild	001-004333/2
-6314	Oxidation/Reduction: Chemical Incompatibility	N/A - the material is not reactive nor does it contain an oxidizing or reducing agent	-----
-6315	Flammability/Flame Extension	N/A - the product does not contain a combustible liquid	-----
-6316	Explosibility	N/A- the product is not potentially explosive based on structure	-----
-6317	Storage Stability	There has been no change in the concentration of the AI under ambient conditions or under accelerated shelf conditions (40°C.) for 30 days in HDPE container	B07/03/009
-6319	Miscibility	The product is completely miscible in mineral oil and forms emulsion in water.	001-004333/2
-6320	Corrosion Characteristics	There have been no observations of reactivity of the liquid or the HDPE container after 30 days in ambient conditions or under accelerated shelf life conditions (40°C.)	B07/03/006
-6321	Dielectric Breakdown Voltage	N/A - the material is not to be used around electrical equipment	-----
-7000	pH	6.00	001-004333/2
-7100	Viscosity	2.3 cP	001-004333/2
-7300	Density/Relative Density/ Bulk Density	0.980 g/mL	001-004333/2





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**SELF-CERTIFICATION STATEMENT FOR THE  
PHYSICAL/CHEMICAL PROPERTIES (PR NOTICE 98-1)**

Product Name: B2E-01

Reg. No./File Symbol No. 75318 -  
(if known) or Company No.

**SELF-CERTIFICATION STATEMENT:**

I certify that the reported information on the "Summary Form" represents a true and accurate record of the test results of studies generated or owned by (Company Name): B2E Biotech LLC

and that the values of the properties reported are reliable.

I further certify that such data was generated in substantial conformity with OPPTS Test Guidelines Series 830 Product Properties, applicable to my product, and in effect at the time of submission.

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(Q), or 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.

Type Applicant's Name:

William K. Mintz

Title:

Manager

Telephone No.

631/537-9797

Applicant's Signature:

Date:

March 1, 2004

EPA Form 8570-37 (07/JAN/1998)

Attach-2

Page 17 of 21 / B03-04-0011

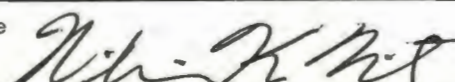


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date March 1, 2004		EPA Reg No./File Symbol 75318-		Page 1 of 1	
Applicant's/Registrant's Name & Address B2E BIOTECH LLC, 500 Mamaroneck Avenue, Suite 201, Harrison, NY 10528		Product B2E-01			
Ingredient (S)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Section 158.155	Product Composition		75318	OWN	
Section 158.160	Description of products used to produce the formulation		75318	OWN	
Section 158.162	Description of formulation process		75318	OWN	
Section 158.175	Certified limits		75318	OWN	
Section 158.180	Enforcement analytical method	457374-05	69554	EXC	
870.1100	Acute oral toxicity in rats	450873-09	74032	EXC	
870.1200	Acute dermal toxicity in rats	450873-10	74032	EXC	
870.1300	Acute inhalation toxicity in rats	450873-11	74032	EXC	
870.2400	Primary eye irritation in rats	450873-12	74032	EXC	
870.2500	Primary skin irritation in rabbits	450873-13	74032	EXC	
870.2600	Dermal sensitization in guinea pigs	450873-13	74032	EXC	
850.2100	Avian acute oral toxicity test	455434-01	74032	EXC	
850.2200	Avian dietary toxicity test	455434-02	74032	EXC	
850.1075	Fish acute toxicity test, Freshwater & Marine	455434-03	74032	EXC	
850.1010	Aquatic Invertebrate acute tox. test, Freshwater Daphnids	455434-04	74032	EXC	
Signature 			Name and Title William K. Mintz, Manager		Date 3/1/04

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



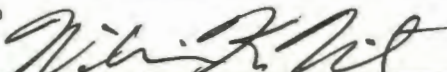


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date March 1, 2004		EPA Reg No./File Symbol 75318-		Page 1 of 1	
Applicant's/Registrant's Name & Address B2E BIOTECH LLC, 500 Mamaroneck Avenue, Suite 201, Harrison, NY 10528		Product B2E-01			
Ingredient (S)-Methoprene					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			75318	OWN	
			75318	OWN	
			75318	OWN	
			75318	OWN	
			69554	EXC	
			74032	EXC	
			74032	EXC	
			74032	EXC	
			74032	EXC	
			74032	EXC	.
			74032	EXC	.
			74032	EXC	.
			74032	EXC	.
			74032	EXC	.
			74032	EXC	.
Signature 			Name and Title William K. Mintz, Manager		Date 3/1/04

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

# Hartz-B2E LLC

500 Mamaroneck Ave. • Suite 201 • Harrison, NY 10528 • USA • Phone: 914-777-3111 • Fax: 914-777-0781

EPA

1004

August 11, 2003

B2E Biotech LLC  
500 Mamaroneck Avenue  
Harrison, NY 10528

## Certificate of Permission

Dear Sirs:

Hartz-B2E LLC hereby grants permission for B2E Biotech LLC to cite the data below for its application for B2E-01:

MRID #	TITLE
450873-09	Acute oral toxicity in rats
450873-10	Acute dermal toxicity in rats
450873-11	Acute inhalation toxicity in rats
450873-12	Primary eye irritation in rats
450873-13	Primary skin Irritation in rabbits
450873-14	Dermal sensitization in guinea pigs
455434-01	Avian Acute Oral Toxicity Test
455434-02	Avian Dietary Toxicity Test
455434-03	Fish Acute Toxicity Test, Freshwater and Marine
455434-04	Aquatic Invertebrate Acute Toxicity Test, Freshwater Daphnids

Sincerely yours,

  
William K. Mintz  
Manager



# B2E Corporation

EPH

500 Mamaroneck Ave. • Suite 201 • Harrison, NY 10528 • USA • Phone: 914-777-1111 • Fax: 914-777-0781

2004

January 13, 2004

B2E Biotech LLC  
500 Mamaroneck Avenue  
Harrison, NY 10528

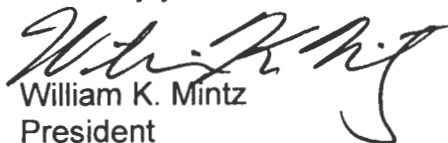
## Certificate of Permission

Dear Sirs:

B2E Corporation hereby grants permission for B2E Biotech LLC to cite the data below for its application for B2E-01:

MRID #	TITLE
457374-05	Enforcement Analytic Method

Sincerely yours,

  
William K. Mintz  
President

# B2E-01 MASTER LABEL

## An Insect Growth Regulator

*(to control insect pests in tobacco processing and storage facilities)*

*(to prevent emergence of adult Sciarid flies in mushroom culture)*

*(to prevent the emergence of stored product insects)*

*(to prevent the emergence of adult filter flies & non-biting midges)*

*(to prevent the emergence of adult floodwater mosquitoes)*

### ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6) . . . . . 33.6%

OTHER INGREDIENTS\* . . . . . 66.4%

Total . . . . . 100.0%

This product contains 2.748 lb/gallon (329.3 grams/liter) (S)-Methoprene active ingredient

EPA Reg No. 75318-

EPA Est. No.

B2E Biotech LLC

500 Mamaroneck Avenue

Harrison, NY 10528

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**See additional precautionary statements**

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### FIRST AID

##### If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
- Call a poison control center or doctor for treatment advice.

##### If on skin

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

##### If swallowed

- Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person.
- Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

### ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of rinsate or equipment washwaters.



## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### STORAGE

Store in a cool place.

### PESTICIDE DISPOSAL

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions. Always read the label before using this product.

In case of an emergency, call Chem-Tel at 1-xxx-xxx-xxxx.

For information visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

### *(Directions for Use for B2E-01 to control insect pests in tobacco processing and storage facilities)*

## FOR PROTECTION OF STORED TOBACCO FROM DAMAGE BY CIGARETTE BEETLE (*LASIODERMA SERRICORNE*) AND TOBACCO MOTH (*EPHESTIA ELUTELLA*)

### INTRODUCTION

B2E-01 is a water based emulsifiable formulation of the insect growth regulator, (S)-Methoprene. It is designed for use as a space spray in cold aerosol generators and in liquid concentrate form as an aqueous emulsified spray. Unlike traditional pesticides, (S)-Methoprene does not immediately kill immature insects; instead, it interferes with the normal insect development process and prevents adult pest emergence. B2E-01, prevents the adult emergence and reproduction of the Cigarette beetle (*Lasioderma serricorne*) and Tobacco moth (*Ephestia elutella*) when used according to label directions.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

#### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment that will achieve uniform dispersal for best treatment results.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for a minimum of 30 minutes (longer if possible) to allow the fine spray mist to settle. Do not remain in treated areas after treating. Ventilate treated areas before reentry. Repeat application as required.

#### APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Repeat application as required.

#### MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.



*(Directions for Use for B2E-01 prevent emergence of adult sciarid flies in mushroom culture)*

## **AN INSECT GROWTH REGULATOR TO PREVENT THE EMERGENCE OF ADULT SCIARID FLIES IN MUSHROOM CULTURE**

### **INTRODUCTION**

S-Methoprene, the active ingredient in **B2E-01** insect growth regulator (IGR), is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of S-Methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. **B2E-01** prevents the emergence of adult Sciarid flies from the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adult flies present at the time of application will not be affected. If high adult fly populations are present initially, use of a conventional adulticide will insure the best overall results. After treatment with **B2E-01**, larvae will continue to develop to the pupal stage where they will die. As **B2E-01** prevents adult fly emergence, adult fly populations will be reduced over time. As maximum control is achieved two weeks after treatment, control assessment should be made at this time for most accurate evaluation.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **Personal Protection Equipment (PPE)**

Some materials that are chemical-resistant to this product are listed below. For more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, such as neoprene rubber ( $\geq 14$  mils), nitrile rubber ( $\geq 14$  mils), barrier laminate, or viton ( $\geq 14$  mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **Engineering Control Statements:**

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)]. The handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

#### **User Safety Recommendations:**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

### **AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses on this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: if the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.



PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber, (≥14 mils), barrier laminated, or viton (≥14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.

## **METHOD, RATE, AND TIMING OF APPLICATION**

For best results, B2E-01 should be incorporated in the mushroom growing medium.

Follow either METHOD A, METHOD B, METHOD C, METHOD D or METHOD E

### **APPLICATION INSTRUCTIONS:**

#### **A. INCORPORATE AT TIME OF CASING**

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft. Make spray application evenly, and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface immediately after placement.

#### **B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING WHEN CASING LAYER IS PLACED ON COMPOST**

##### **In Compost:**

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution. Spray on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

##### **In Casing:**

Mix B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application, On Compost:**

Apply B2E-01 12 to 13 days after spawning. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

##### **Second Application, In Casing:**

Apply B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS**

##### **First Application, In Casing:**

Apply B2E-01 at the rate of 5½ fl. oz. per 1,000 sq. ft. in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

##### **Second Application, On casing surface just prior to break:**

Apply B2E-01 at the rate of 2¼ fl. oz. of per 1,000 sq. ft. in adequate water for even distribution as a surface drench prior to first break of mushrooms.

#### **E. DELAYED CASING SURFACE DRENCH**

### **APPLICATION INSTRUCTIONS:**

#### **A. Surface drench 7 days after casing**

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### **B. Surface drench 7 days and 14 days after casing**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application on Casing:**

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¼ fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### Second Application on Casing:

Apply B2E-01 14 days after casing. Drench B2E-01 evenly on the surface at the rate of 2½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

### MIXING AND HANDLING INSTRUCTIONS

1. Shake container before using.
2. Add the measured amount of B2E-01 to a spray tank partially filled with water, mix, and complete filling with recommended quantity of water.
3. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

### EFFECT ON MUSHROOMS

In most cases, treatment with B2E-01 has a beneficial effect on mushroom yield by reducing Sciarid fly larval damage. As mushroom production practices differ among growers, the user should conduct small plots treatments to verify that reduced crop yields will not occur under cultural conditions used.

**(Directions for Use for B2E-01 to prevent the emergence of stored product insects)**

### AN INSECT GROWTH REGULATOR TO CONTROL STORED PRODUCT INSECTS

#### INTRODUCTION

The active ingredient in B2E-01, (S)-Methoprene, protects stored grains from damaging insects by preventing insect development and adult emergence. Unlike traditional pesticides, B2E-01 is not an adulticide, but its residual activity interferes with reproduction and prevents treated larvae from developing into adults. B2E-01, when used according to the label directions, prevents regeneration of the following insects: Almond Moth (*Ephestia cautella*), Indian Meal Moth (*Plodia interpunctella*), Cigarette Beetle (*Lasioderma serricorne*), Lesser Grain Beetle (*Rhyzopertha dominica*), Sawtooth Grain Beetle (*Oryzaephilus surinamensis*), Merchant Grain Beetle (*Oryzaephilus mercator*), Red Flour Beetle (*Tribolium castaneum*), and Confused Flour Beetle (*Tribolium confusum*). Existing insect populations should be treated with an approved adulticide to kill adult pests before applying B2E-01 for residual protection. If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

**Stored Grain:** For maximum protection of stored food, feed, oil, and seed grains from stored grain insect damage, thoroughly clean and treat grain storage areas prior to storage of grain. B2E-01 may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 to 5 ppm for this application. Do not flood top-dress area.

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED:** Dilute B2E-01 with water and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of B2E-01 on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply. Do not use rate less than 1 ppm. B2E-01 is to be applied in solution in accordance with the general directions to stored products at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of B2E-01. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

	5 ppm		2.5 ppm		1 ppm	
	fl oz	ml	fl oz	ml	fl oz	ml
Wheat	7.70	228	4.0	114	1.54	46
Corn	7.10	212	3.5	106	1.42	43
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43
Barley	6.10	182	3.0	91	1.22	37
Rice	5.70	170	3.0	85	1.10	34
Oats	4.10	121	2.0	61	0.80	25
Peanuts	3.85	115	2.0	60	0.80	24



## USE PRECAUTIONS:

- Apply B2E-01 grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of B2E-01 to a spray tank partially filled with water mix, and complete filling with specified quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Do not treat at extremely dusty sites. B2E-01 may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins, or other stored commodity areas. For application of B2E-01 as a fogging or space spray, use the following directions.

## APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment. Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

## APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

## MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 48 hours of mixing. Agitate before each use.

*(Directions for Use for B2E-01 to prevent the emergence of adult filter flies & non-biting midges)*

**PREVENTS THE EMERGENCE OF ADULT FILTER FLIES AND MIDGES -  
KEEPS INFESTATIONS UNDER CONTROL**

## INTRODUCTION

B2E-01 is a unique water based product that controls filter flies (*Psychodidae*), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. B2E-01 contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. B2E-01 does not control adults but prevents the larval stage from developing into flying adults. B2E-01 keeps pest infestations under control by stopping the reproduction cycle, without shutting down your treatment facility. Regular use of B2E-01 prevents these pests from developing into annoying infestations.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

## MIXING AND HANDLING INSTRUCTIONS:

Partially fill application tank with water; then add the specified amount of B2E-01, and complete filling with recommended quantity of water. Agitate before application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

## RECOMMENDED APPLICATIONS

### WASTE WATER TREATMENT FACILITY PESTS

Use B2E-01 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

### WHAT TO EXPECT IN CONTINUOUS FLOW WASTE WATER TREATMENT FACILITIES

To achieve effective results, B2E-01 must be applied to continuous flow systems on a daily basis for at least two weeks. A gradual reduction in the number of adult pests will be seen over a 7 day period with significant reduction seen after 14 days of treatment. Failure to apply B2E-01 daily may produce erratic results. Very heavy infestations often require slightly longer to achieve the desired control level. Since the mode of action



of B2E-01 is to prevent adult emergence, pupa and adults present at the time of initial application will complete their life cycle. Pest populations can be expected to rebound within 2-4 weeks following the last day of treatment. Insect monitoring traps, such as sticky paper can be used to monitor pest population rebound to determine when re-treatment should be initiated. Re-treatment intervals will vary depending on treatment plant design and size.

#### **SLUDGE OR SOLID WASTE APPLICATIONS**

For sludge solid waste applications, a high rate is recommended. Apply dilution until the drying beds have been filled, then stop the application. Applications should be made at the influent side where the sludge or solids enter into the drying beds. Application of B2E-01 to solids will prevent pest insect emergence thereby keeping infestations under control.

#### **METHODS OF APPLICATION**

Dilute B2E-01 with water prior to use. Apply B2E-01 by use of a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence product dilution. Treatments should be made over a 4 hour period during the lowest flow period of the day. It is important to calibrate delivery devices to dispense the required amount of B2E-01 over a 4 hour period to ensure effective control. In the case of sludge beds, B2E-01 should be applied until the beds have been filled.

#### **APPLICATION RATES**

To control waste water pests, apply 3 - 5 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply at the influent side over a 4 hour period during the lowest flow period of the day. For best results, make the application on a daily basis for two weeks without interruption.

#### **APPLICATION SITES**

Make applications of B2E-01 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem. Make B2E-01 applications as the sewage enters (influent areas) the waste water treatment area. Failure to add the material at the influent side may produce erratic results.

*(Directions for Use for B2E-01 to prevent the emergence of adult floodwater mosquitoes)*

### **PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES**

#### **INTRODUCTION**

B2E-01 provides effective levels of S-Methoprene insect growth regulator to control single broods of floodwater mosquitoes. B2E-01 prevents the emergence of adult floodwater mosquitoes (*Aedes*, *Ochloratus* and *Psorophora*) from treated water. Treated larvae continue to develop normally to the pupal stage where they die. The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **MIXING AND HANDLING INSTRUCTIONS**

1. B2E-01 is a water emulsifiable concentrate which requires agitation for uniform suspension. Separation may occur on standing, thus agitate prior to application.
2. Use clean equipment.
3. Partially fill spray tank with water; then add B2E-01, agitate and complete filling.
4. Spray solutions should be used within 48 hours; always agitate before and during spraying.

#### **RECOMMENDED APPLICATIONS**

B2E-01 should be applied to 4th instar floodwater mosquito larvae prior to pupation to prevent adult emergence. As 4<sup>th</sup> instar larvae stop feeding 12 to 18 hours before pupation, it is essential that treatments be made before cessation of feeding. Apply B2E-01 in the late afternoon or evening to extend control activity. Correct treatment timing is very important for best results. Treated larvae continue normal development to the pupal stage where they die. The active ingredient has no effect when applied to pupae or adult mosquitoes.



## APPLICATION RATES

Apply 0.5 ounce to 1.5 ounces (15 to 44 ml) of **B2E-01** per acre in water. Use lower rates when applying to shallow water (<1 foot deep). Use higher application rates to treat deeper water (>1 foot deep), to sites with dense vegetation, or when application conditions require treatments to be made earlier in development than recommended

## APPLICATION SITES

### PASTURES:

**B2E-01** may be applied, without removal of grazing livestock. **B2E-01** may be applied to 4th instar larvae of pasture mosquitoes. **B2E-01** treatment may be repeated as needed with each flooding.

### INTERMITTENTLY FLOODED NONCROP AREAS:

**B2E-01** may be applied to floodwater mosquito habits such as: freshwater swamps and marshes, salt marshes, woodland pools and meadows, dredging spoil sites, drainage areas, waste treatment and settling ponds, ditches and other natural and man made depressions.

### CROP AREAS:

Apply **B2E-01** to irrigated croplands to prevent adult mosquito emergence. Examples of such sites are: vineyards, rice fields (including wild rice), orchards, and berry fields and bogs. Irrigated pastures may be treated after each flooding without the removal of livestock.

### DENSE VEGETATION OR CANOPY AREAS:

Use **B2E-01** to make granules on sand or other carrier following preparation instructions detailed on the label. Apply **B2E-01** Granules using standard granular dispersal equipment.

## AERIAL & GROUND

Use the recommended amount of **B2E-01** listed below in sufficient water to give complete coverage. Do not apply when weather conditions will cause drift from the areas to be treated. Use **B2E-01** Granules to make treatments under windy conditions or to dense vegetation.

### To Make B2E-01 Granules:

Granules can be made using washed, dry sand or other carriers. Apply **B2E-01** to the granule quantity to be applied per acre. For example, to apply 1.0 fl. oz./acre dosage rate on 5 pounds of granules per acre: Add 98 pounds of washed dry sand into a small rotary cement mixer. Tilt mixer to an angle 20° above horizontal. Measure out 20 fl. oz. of **B2E-01**, and add to a sprayer equipped with a flat fan nozzle. Pressurize sprayer and turn on mixer. Spray **B2E-01** on the rolling face of the sand until it is evenly dampened. Mix for 2 minutes, then add a drying agent (Microcel E or Hisil 233) as needed, to achieve a dry, free flowing granule. Discharge and bag. Apply within 72 hours.

Refer to table below for the number of ounces used to make 100 pound batches of granules applied at different rates per acre.

Dosage Rate Oz./Acre	Granule Application Rate/Acre (Lbs.)	Ounces of B2E-01 applied to granules
0.5	2.5	20
0.5	5.0	10
0.5	10.0	5
1.0	2.5	40
1.0	5.0	20
1.0	10.0	10
1.5	2.5	60
1.5	5.0	30
1.5	10.0	15

## B2E-01 MASTER LABEL

### An Insect Growth Regulator

*(to control insect pests in tobacco processing and storage facilities)*

*(to prevent emergence of adult Sciarid flies in mushroom culture)*

*(to prevent the emergence of stored product insects)*

*(to prevent the emergence of adult filter flies & non-biting midges)*

*(to prevent the emergence of adult floodwater mosquitoes)*

#### ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6)..... 33.6%

OTHER INGREDIENTS\*..... 66.4%

Total:..... 100.0%

This product contains 2.748 lb/gallon (329.3 grams/liter) (S)-Methoprene active ingredient

EPA Reg No. 75318-

EPA Est. No.

B2E Biotech LLC

500 Mamaroneck Avenue

Harrison, NY 10528

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**See additional precautionary statements**

#### PRECAUTIONARY STATEMENTS

##### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### FIRST AID

##### If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
- Call a poison control center or doctor for treatment advice.

##### If on skin

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

##### If swallowed

- Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person.
- Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

#### ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of rinsate or equipment washwaters.



## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### STORAGE

Store in a cool place.

### PESTICIDE DISPOSAL

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions. Always read the label before using this product.

In case of an emergency, call Chem-Tel at 1-xxx-xxx-xxxx.

For information visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

### *(Directions for Use for B2E-01 to control insect pests in tobacco processing and storage facilities)*

## FOR PROTECTION OF STORED TOBACCO FROM DAMAGE BY CIGARETTE BEETLE (*LASIODERMA SERRICORNE*) AND TOBACCO MOTH (*EPHESTIA ELUTELLA*)

### INTRODUCTION

B2E-01 is a water based emulsifiable formulation of the insect growth regulator, (S)-Methoprene. It is designed for use as a space spray in cold aerosol generators and in liquid concentrate form as an aqueous emulsified spray. Unlike traditional pesticides, (S)-Methoprene does not immediately kill immature insects; instead, it interferes with the normal insect development process and prevents adult pest emergence. B2E-01, prevents the adult emergence and reproduction of the Cigarette beetle (*Lasioderma serricorne*) and Tobacco moth (*Ephestia elutella*) when used according to label directions.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

#### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment that will achieve uniform dispersal for best treatment results.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for a minimum of 30 minutes (longer if possible) to allow the fine spray mist to settle. Do not remain in treated areas after treating. Ventilate treated areas before reentry. Repeat application as required.

#### APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Repeat application as required.

#### MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.



***(Directions for Use for B2E-01 prevent emergence of adult sciarid flies in mushroom culture)***

**AN INSECT GROWTH REGULATOR TO PREVENT THE EMERGENCE OF ADULT SCIARID FLIES IN MUSHROOM CULTURE**

**INTRODUCTION**

S-Methoprene, the active ingredient in **B2E-01** insect growth regulator (IGR), is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of S-Methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. **B2E-01** prevents the emergence of adult Sciarid flies from the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adult flies present at the time of application will not be affected. If high adult fly populations are present initially, use of a conventional adulticide will insure the best overall results. After treatment with **B2E-01**, larvae will continue to develop to the pupal stage where they will die. As **B2E-01** prevents adult fly emergence, adult fly populations will be reduced over time. As maximum control is achieved two weeks after treatment, control assessment should be made at this time for most accurate evaluation.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**Personal Protection Equipment (PPE)**

Some materials that are chemical-resistant to this product are listed below. For more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber (≥14 mils), barrier laminate, or viton (≥14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**Engineering Control Statements:**

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)]. The handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

**User Safety Recommendations:**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses on this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: if the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.



PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber, (≥14 mils), barrier laminated, or viton (≥14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.

## **METHOD, RATE, AND TIMING OF APPLICATION**

For best results, B2E-01 should be incorporated in the mushroom growing medium.

Follow either METHOD A, METHOD B, METHOD C, METHOD D or METHOD E

### **APPLICATION INSTRUCTIONS:**

#### **A. INCORPORATE AT TIME OF CASING**

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft. Make spray application evenly, and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface immediately after placement.

#### **B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING WHEN CASING LAYER IS PLACED ON COMPOST**

##### **In Compost:**

Mix B2E-01 at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution. Spray on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

##### **In Casing:**

Mix B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application, On Compost:**

Apply B2E-01 12 to 13 days after spawning. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

##### **Second Application, In Casing:**

Apply B2E-01 at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS**

##### **First Application, In Casing:**

Apply B2E-01 at the rate of 5½ fl. oz. per 1,000 sq. ft. in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

##### **Second Application, On casing surface just prior to break:**

Apply B2E-01 at the rate of 2¼ fl. oz. of per 1,000 sq. ft. in adequate water for even distribution as a surface drench prior to first break of mushrooms.

#### **E. DELAYED CASING SURFACE DRENCH**

### **APPLICATION INSTRUCTIONS:**

#### **A. Surface drench 7 days after casing**

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### **B. Surface drench 7 days and 14 days after casing**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application on Casing:**

Apply B2E-01 7 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¼ fl. oz. per 1,000 sq ft in adequate water for even distribution.



#### Second Application on Casing:

Apply B2E-01 14 days after casing. Drench B2E-01 evenly on the surface at the rate of 2½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

### MIXING AND HANDLING INSTRUCTIONS

1. Shake container before using.
2. Add the measured amount of B2E-01 to a spray tank partially filled with water, mix, and complete filling with recommended quantity of water.
3. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

### EFFECT ON MUSHROOMS

In most cases, treatment with B2E-01 has a beneficial effect on mushroom yield by reducing Sciarid fly larval damage. As mushroom production practices differ among growers, the user should conduct small plots treatments to verify that reduced crop yields will not occur under cultural conditions used.

### (Directions for Use for B2E-01 to prevent the emergence of stored product insects)

### AN INSECT GROWTH REGULATOR TO CONTROL STORED PRODUCT INSECTS

#### INTRODUCTION

The active ingredient in B2E-01, (S)-Methoprene, protects stored grains from damaging insects by preventing insect development and adult emergence. Unlike traditional pesticides, B2E-01 is not an adulticide, but its residual activity interferes with reproduction and prevents treated larvae from developing into adults. B2E-01, when used according to the label directions, prevents regeneration of the following insects: Almond Moth (*Ephesia cautella*), Indian Meal Moth (*Plodia interpunctella*), Cigarette Beetle (*Lasioderma serricorne*), Lesser Grain Beetle (*Rhyzopertha dominica*), Sawtooth Grain Beetle (*Oryzaephilus surinamensis*), Merchant Grain Beetle (*Oryzaephilus mercator*), Red Flour Beetle (*Tribolium castaneum*), and Confused Flour Beetle (*Tribolium confusum*). Existing insect populations should be treated with an approved adulticide to kill adult pests before applying B2E-01 for residual protection. If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

**Stored Grain:** For maximum protection of stored food, feed, oil, and seed grains from stored grain insect damage, thoroughly clean and treat grain storage areas prior to storage of grain. B2E-01 may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 to 5 ppm for this application. Do not flood top-dress area.

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED:** Dilute B2E-01 with water and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of B2E-01 on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply. Do not use rate less than 1 ppm. B2E-01 is to be applied in solution in accordance with the general directions to stored products at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of B2E-01. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

	5 ppm		2.5 ppm		1 ppm	
	fl oz	ml	fl oz	ml	fl oz	ml
Wheat	7.70	228	4.0	114	1.54	46
Corn	7.10	212	3.5	106	1.42	43
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43
Barley	6.10	182	3.0	91	1.22	37
Rice	5.70	170	3.0	85	1.10	34
Oats	4.10	121	2.0	61	0.80	25
Peanuts	3.85	115	2.0	60	0.80	24



## USE PRECAUTIONS:

- Apply B2E-01 grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of B2E-01 to a spray tank partially filled with water mix, and complete filling with specified quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Do not treat at extremely dusty sites. B2E-01 may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins, or other stored commodity areas. For application of B2E-01 as a fogging or space spray, use the following directions.

## APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment. Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

## APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

## MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 48 hours of mixing. Agitate before each use.

*(Directions for Use for B2E-01 to prevent the emergence of adult filter flies & non-biting midges)*

## PREVENTS THE EMERGENCE OF ADULT FILTER FLIES AND MIDGES - KEEPS INFESTATIONS UNDER CONTROL

### INTRODUCTION

B2E-01 is a unique water based product that controls filter flies (*Psychodidae*), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. B2E-01 contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. B2E-01 does not control adults but prevents the larval stage from developing into flying adults. B2E-01 keeps pest infestations under control by stopping the reproduction cycle, without shutting down your treatment facility. Regular use of B2E-01 prevents these pests from developing into annoying infestations.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### MIXING AND HANDLING INSTRUCTIONS:

Partially fill application tank with water; then add the specified amount of B2E-01, and complete filling with recommended quantity of water. Agitate before application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

### RECOMMENDED APPLICATIONS

#### WASTE WATER TREATMENT FACILITY PESTS

Use B2E-01 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

#### WHAT TO EXPECT IN CONTINUOUS FLOW WASTE WATER TREATMENT FACILITIES

To achieve effective results, B2E-01 must be applied to continuous flow systems on a daily basis for at least two weeks. A gradual reduction in the number of adult pests will be seen over a 7 day period with significant reduction seen after 14 days of treatment. Failure to apply B2E-01 daily may produce erratic results. Very heavy infestations often require slightly longer to achieve the desired control level. Since the mode of action



of B2E-01 is to prevent adult emergence, pupa and adults present at the time of initial application will complete their life cycle. Pest populations can be expected to rebound within 2-4 weeks following the last day of treatment. Insect monitoring traps, such as sticky paper can be used to monitor pest population rebound to determine when re-treatment should be initiated. Re-treatment intervals will vary depending on treatment plant design and size.

#### **SLUDGE OR SOLID WASTE APPLICATIONS**

For sludge solid waste applications, a high rate is recommended. Apply dilution until the drying beds have been filled, then stop the application. Applications should be made at the influent side where the sludge or solids enter into the drying beds. Application of B2E-01 to solids will prevent pest insect emergence thereby keeping infestations under control.

#### **METHODS OF APPLICATION**

Dilute B2E-01 with water prior to use. Apply B2E-01 by use of a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence product dilution. Treatments should be made over a 4 hour period during the lowest flow period of the day. It is important to calibrate delivery devices to dispense the required amount of B2E-01 over a 4 hour period to ensure effective control. In the case of sludge beds, B2E-01 should be applied until the beds have been filled.

#### **APPLICATION RATES**

To control waste water pests, apply 3 - 5 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply at the influent side over a 4 hour period during the lowest flow period of the day. For best results, make the application on a daily basis for two weeks without interruption.

#### **APPLICATION SITES**

Make applications of B2E-01 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem. Make B2E-01 applications as the sewage enters (influent areas) the waste water treatment area. Failure to add the material at the influent side may produce erratic results.

*(Directions for Use for B2E-01 to prevent the emergence of adult floodwater mosquitoes)*

### **PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES**

#### **INTRODUCTION**

B2E-01 provides effective levels of S-Methoprene insect growth regulator to control single broods of floodwater mosquitoes. B2E-01 prevents the emergence of adult floodwater mosquitoes (*Aedes*, *Ochloratus* and *Psorophora*) from treated water. Treated larvae continue to develop normally to the pupal stage where they die. The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **MIXING AND HANDLING INSTRUCTIONS**

1. B2E-01 is a water emulsifiable concentrate which requires agitation for uniform suspension. Separation may occur on standing, thus agitate prior to application.
2. Use clean equipment.
3. Partially fill spray tank with water; then add B2E-01, agitate and complete filling.
4. Spray solutions should be used within 48 hours; always agitate before and during spraying.

#### **RECOMMENDED APPLICATIONS**

B2E-01 should be applied to 4th instar floodwater mosquito larvae prior to pupation to prevent adult emergence. As 4<sup>th</sup> instar larvae stop feeding 12 to 18 hours before pupation, it is essential that treatments be made before cessation of feeding. Apply B2E-01 in the late afternoon or evening to extend control activity. Correct treatment timing is very important for best results. Treated larvae continue normal development to the pupal stage where they die. The active ingredient has no effect when applied to pupae or adult mosquitoes.



## APPLICATION RATES

Apply 0.5 ounce to 1.5 ounces (15 to 44 ml) of **B2E-01** per acre in water. Use lower rates when applying to shallow water (<1 foot deep). Use higher application rates to treat deeper water (>1 foot deep), to sites with dense vegetation, or when application conditions require treatments to be made earlier in development than recommended

## APPLICATION SITES

### PASTURES:

**B2E-01** may be applied, without removal of grazing livestock. **B2E-01** may be applied to 4th instar larvae of pasture mosquitoes. **B2E-01** treatment may be repeated as needed with each flooding.

### INTERMITTENTLY FLOODED NONCROP AREAS:

**B2E-01** may be applied to floodwater mosquito habits such as: freshwater swamps and marshes, salt marshes, woodland pools and meadows, dredging spoil sites, drainage areas, waste treatment and settling ponds, ditches and other natural and man made depressions.

### CROP AREAS:

Apply **B2E-01** to irrigated croplands to prevent adult mosquito emergence. Examples of such sites are: vineyards, rice fields (including wild rice), orchards, and berry fields and bogs. Irrigated pastures may be treated after each flooding without the removal of livestock.

### DENSE VEGETATION OR CANOPY AREAS:

Use **B2E-01** to make granules on sand or other carrier following preparation instructions detailed on the label. Apply **B2E-01** Granules using standard granular dispersal equipment.

## AERIAL & GROUND

Use the recommended amount of **B2E-01** listed below in sufficient water to give complete coverage. Do not apply when weather conditions will cause drift from the areas to be treated. Use **B2E-01** Granules to make treatments under windy conditions or to dense vegetation.

### To Make B2E-01 Granules:

Granules can be made using washed, dry sand or other carriers. Apply **B2E-01** to the granule quantity to be applied per acre. For example, to apply 1.0 fl. oz./acre dosage rate on 5 pounds of granules per acre: Add 98 pounds of washed dry sand into a small rotary cement mixer. Tilt mixer to an angle 20° above horizontal. Measure out 20 fl. oz. of **B2E-01**, and add to a sprayer equipped with a flat fan nozzle. Pressurize sprayer and turn on mixer. Spray **B2E-01** on the rolling face of the sand until it is evenly dampened. Mix for 2 minutes, then add a drying agent (Microcel E or Hisil 233) as needed, to achieve a dry, free flowing granule. Discharge and bag. Apply within 72 hours.

Refer to table below for the number of ounces used to make 100 pound batches of granules applied at different rates per acre.

Dosage Rate Oz./Acre	Granule Application Rate/Acre (Lbs.)	Ounces of B2E-01 applied to granules
0.5	2.5	20
0.5	5.0	10
0.5	10.0	5
1.0	2.5	40
1.0	5.0	20
1.0	10.0	10
1.5	2.5	60
1.5	5.0	30
1.5	10.0	15

# B2E-01 MASTER LABEL

## An Insect Growth Regulator

*(to control insect pests in tobacco processing and storage facilities)*

*(to prevent emergence of adult Sciarid flies in mushroom culture)*

*(to prevent the emergence of stored product insects)*

*(to prevent the emergence of adult filter flies & non-biting midges)*

*(to prevent the emergence of adult floodwater mosquitoes)*

### ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6) . . . . . 33.6%

OTHER INGREDIENTS\* . . . . . 66.4%

Total . . . . . 100.0%

This product contains 2.748 lb/gallon (329.3 grams/liter) (S)-Methoprene active ingredient

EPA Reg No. 75318-

EPA Est. No.

B2E Biotech LLC

500 Mamaroneck Avenue

Harrison, NY 10528

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**See additional precautionary statements**

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### FIRST AID

<b>If in eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If on skin</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If swallowed</b>	<ul style="list-style-type: none"><li>• Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

### ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of rinsate or equipment washwaters.



## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### STORAGE

Store in a cool place.

### PESTICIDE DISPOSAL

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions. Always read the label before using this product.

In case of an emergency, call Chem-Tel at 1-xxx-xxx-xxxx.

For information visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

### *(Directions for Use for B2E-01 to control insect pests in tobacco processing and storage facilities)*

## FOR PROTECTION OF STORED TOBACCO FROM DAMAGE BY CIGARETTE BEETLE (*LASIODERMA SERRICORNE*) AND TOBACCO MOTH (*EPHESTIA ELUTELLA*)

### INTRODUCTION

B2E-01 is a water based emulsifiable formulation of the insect growth regulator, (S)-Methoprene. It is designed for use as a space spray in cold aerosol generators and in liquid concentrate form as an aqueous emulsified spray. Unlike traditional pesticides, (S)-Methoprene does not immediately kill immature insects; instead, it interferes with the normal insect development process and prevents adult pest emergence. B2E-01, prevents the adult emergence and reproduction of the Cigarette beetle (*Lasioderma serricorne*) and Tobacco moth (*Ephestia elutella*) when used according to label directions.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

#### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment that will achieve uniform dispersal for best treatment results.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for a minimum of 30 minutes (longer if possible) to allow the fine spray mist to settle. Do not remain in treated areas after treating. Ventilate treated areas before reentry. Repeat application as required.

#### APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Repeat application as required.

#### MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.



***(Directions for Use for B2E-01 prevent emergence of adult sciarid flies in mushroom culture)***

**AN INSECT GROWTH REGULATOR TO PREVENT THE EMERGENCE OF ADULT SCIARID FLIES IN MUSHROOM CULTURE**

**INTRODUCTION**

S-Methoprene, the active ingredient in B2E-01 insect growth regulator (IGR), is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of S-Methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. B2E-01 prevents the emergence of adult Sciarid flies from the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adult flies present at the time of application will not be affected. If high adult fly populations are present initially, use of a conventional adulticide will insure the best overall results. After treatment with B2E-01, larvae will continue to develop to the pupal stage where they will die. As B2E-01 prevents adult fly emergence, adult fly populations will be reduced over time. As maximum control is achieved two weeks after treatment, control assessment should be made at this time for most accurate evaluation.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**Personal Protection Equipment (PPE)**

Some materials that are chemical-resistant to this product are listed below. For more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber (≥14 mils), barrier laminate, or viton (≥14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**Engineering Control Statements:**

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)]. The handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

**User Safety Recommendations:**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses on this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: if the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.



PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber, (≥14 mils), barrier laminated, or viton (≥14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.

## **METHOD, RATE, AND TIMING OF APPLICATION**

For best results, **B2E-01** should be incorporated in the mushroom growing medium.

Follow either METHOD A, METHOD B, METHOD C, METHOD D or METHOD E

### **APPLICATION INSTRUCTIONS:**

#### **A. INCORPORATE AT TIME OF CASING**

Mix **B2E-01** at the rate of 5½ fl. oz. per 1,000 sq ft. Make spray application evenly, and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface immediately after placement.

#### **B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING WHEN CASING LAYER IS PLACED ON COMPOST**

##### **In Compost:**

Mix **B2E-01** at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution. Spray on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

##### **In Casing:**

Mix **B2E-01** at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application, On Compost:**

Apply **B2E-01** 12 to 13 days after spawning. Drench **B2E-01** evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

##### **Second Application, In Casing:**

Apply **B2E-01** at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS**

##### **First Application, In Casing:**

Apply **B2E-01** at the rate of 5½ fl. oz. per 1,000 sq. ft. in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

##### **Second Application, On casing surface just prior to break:**

Apply **B2E-01** at the rate of 2¼ fl. oz. of per 1,000 sq. ft. in adequate water for even distribution as a surface drench prior to first break of mushrooms.

#### **E. DELAYED CASING SURFACE DRENCH**

### **APPLICATION INSTRUCTIONS:**

#### **A. Surface drench 7 days after casing**

Apply **B2E-01** 7 days after casing. Drench **B2E-01** evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### **B. Surface drench 7 days and 14 days after casing**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application on Casing:**

Apply **B2E-01** 7 days after casing. Drench **B2E-01** evenly on the surface at the rate of 2¼ fl. oz. per 1,000 sq ft in adequate water for even distribution.

### Second Application on Casing:

Apply B2E-01 14 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.

## MIXING AND HANDLING INSTRUCTIONS

1. Shake container before using.
2. Add the measured amount of B2E-01 to a spray tank partially filled with water, mix, and complete filling with recommended quantity of water.
3. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## EFFECT ON MUSHROOMS

In most cases, treatment with B2E-01 has a beneficial effect on mushroom yield by reducing Sciarid fly larval damage. As mushroom production practices differ among growers, the user should conduct small plots treatments to verify that reduced crop yields will not occur under cultural conditions used.

### *(Directions for Use for B2E-01 to prevent the emergence of stored product insects)*

## AN INSECT GROWTH REGULATOR TO CONTROL STORED PRODUCT INSECTS

### INTRODUCTION

The active ingredient in B2E-01, (S)-Methoprene, protects stored grains from damaging insects by preventing insect development and adult emergence. Unlike traditional pesticides, B2E-01 is not an adulticide, but its residual activity interferes with reproduction and prevents treated larvae from developing into adults. B2E-01, when used according to the label directions, prevents regeneration of the following insects: Almond Moth (*Ephestia cautella*), Indian Meal Moth (*Plodia interpunctella*), Cigarette Beetle (*Lasioderma serricorne*), Lesser Grain Beetle (*Rhyzopertha dominica*), Sawtooth Grain Beetle (*Oryzaephilus surinamensis*), Merchant Grain Beetle (*Oryzaephilus mercator*), Red Flour Beetle (*Tribolium castaneum*), and Confused Flour Beetle (*Tribolium confusum*). Existing insect populations should be treated with an approved adulticide to kill adult pests before applying B2E-01 for residual protection. If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

**Stored Grain:** For maximum protection of stored food, feed, oil, and seed grains from stored grain insect damage, thoroughly clean and treat grain storage areas prior to storage of grain. B2E-01 may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 to 5 ppm for this application. Do not flood top-dress area.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED:** Dilute B2E-01 with water and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of B2E-01 on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply. Do not use rate less than 1 ppm. B2E-01 is to be applied in solution in accordance with the general directions to stored products at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of B2E-01. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

	5 ppm		2.5 ppm		1 ppm	
	fl oz	ml	fl oz	ml	fl oz	ml
Wheat	7.70	228	4.0	114	1.54	46
Corn	7.10	212	3.5	106	1.42	43
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43
Barley	6.10	182	3.0	91	1.22	37
Rice	5.70	170	3.0	85	1.10	34
Oats	4.10	121	2.0	61	0.80	25
Peanuts	3.85	115	2.0	60	0.80	24



## **USE PRECAUTIONS:**

- Apply B2E-01 grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of B2E-01 to a spray tank partially filled with water mix, and complete filling with specified quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Do not treat at extremely dusty sites. B2E-01 may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins, or other stored commodity areas. For application of B2E-01 as a fogging or space spray, use the following directions.

## **APPLICATION WITH COLD AEROSOL GENERATORS**

Apply B2E-01 as a mist or aerosol. Dilute with water following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment. Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

## **APPLICATION AS AN AQUEOUS SPRAY**

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

## **MIXING INSTRUCTIONS**

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 48 hours of mixing. Agitate before each use.

*(Directions for Use for B2E-01 to prevent the emergence of adult filter flies & non-biting midges)*

## **PREVENTS THE EMERGENCE OF ADULT FILTER FLIES AND MIDGES - KEEPS INFESTATIONS UNDER CONTROL**

### **INTRODUCTION**

B2E-01 is a unique water based product that controls filter flies (*Psychodidae*), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. B2E-01 contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. B2E-01 does not control adults but prevents the larval stage from developing into flying adults. B2E-01 keeps pest infestations under control by stopping the reproduction cycle, without shutting down your treatment facility. Regular use of B2E-01 prevents these pests from developing into annoying infestations.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### **MIXING AND HANDLING INSTRUCTIONS:**

Partially fill application tank with water; then add the specified amount of B2E-01, and complete filling with recommended quantity of water. Agitate before application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

### **RECOMMENDED APPLICATIONS**

#### **WASTE WATER TREATMENT FACILITY PESTS**

Use B2E-01 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

#### **WHAT TO EXPECT IN CONTINUOUS FLOW WASTE WATER TREATMENT FACILITIES**

To achieve effective results, B2E-01 must be applied to continuous flow systems on a daily basis for at least two weeks. A gradual reduction in the number of adult pests will be seen over a 7 day period with significant reduction seen after 14 days of treatment. Failure to apply B2E-01 daily may produce erratic results. Very heavy infestations often require slightly longer to achieve the desired control level. Since the mode of action



of B2E-01 is to prevent adult emergence, pupa and adults present at the time of initial application will complete their life cycle. Pest populations can be expected to rebound within 2-4 weeks following the last day of treatment. Insect monitoring traps, such as sticky paper can be used to monitor pest population rebound to determine when re-treatment should be initiated. Re-treatment intervals will vary depending on treatment plant design and size.

#### **SLUDGE OR SOLID WASTE APPLICATIONS**

For sludge solid waste applications, a high rate is recommended. Apply dilution until the drying beds have been filled, then stop the application. Applications should be made at the influent side where the sludge or solids enter into the drying beds. Application of B2E-01 to solids will prevent pest insect emergence thereby keeping infestations under control.

#### **METHODS OF APPLICATION**

Dilute B2E-01 with water prior to use. Apply B2E-01 by use of a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence product dilution. Treatments should be made over a 4 hour period during the lowest flow period of the day. It is important to calibrate delivery devices to dispense the required amount of B2E-01 over a 4 hour period to ensure effective control. In the case of sludge beds, B2E-01 should be applied until the beds have been filled.

#### **APPLICATION RATES**

To control waste water pests, apply 3 - 5 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply at the influent side over a 4 hour period during the lowest flow period of the day. For best results, make the application on a daily basis for two weeks without interruption.

#### **APPLICATION SITES**

Make applications of B2E-01 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem. Make B2E-01 applications as the sewage enters (influent areas) the waste water treatment area. Failure to add the material at the influent side may produce erratic results.

*(Directions for Use for B2E-01 to prevent the emergence of adult floodwater mosquitoes)*

### **PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES**

#### **INTRODUCTION**

B2E-01 provides effective levels of S-Methoprene insect growth regulator to control single broods of floodwater mosquitoes. B2E-01 prevents the emergence of adult floodwater mosquitoes (*Aedes*, *Ochloratus* and *Psorophora*) from treated water. Treated larvae continue to develop normally to the pupal stage where they die. The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **MIXING AND HANDLING INSTRUCTIONS**

1. B2E-01 is a water emulsifiable concentrate which requires agitation for uniform suspension. Separation may occur on standing, thus agitate prior to application.
2. Use clean equipment.
3. Partially fill spray tank with water; then add B2E-01, agitate and complete filling.
4. Spray solutions should be used within 48 hours; always agitate before and during spraying.

#### **RECOMMENDED APPLICATIONS**

B2E-01 should be applied to 4th instar floodwater mosquito larvae prior to pupation to prevent adult emergence. As 4<sup>th</sup> instar larvae stop feeding 12 to 18 hours before pupation, it is essential that treatments be made before cessation of feeding. Apply B2E-01 in the late afternoon or evening to extend control activity. Correct treatment timing is very important for best results. Treated larvae continue normal development to the pupal stage where they die. The active ingredient has no effect when applied to pupae or adult mosquitoes.



## APPLICATION RATES

Apply 0.5 ounce to 1.5 ounces (15 to 44 ml) of **B2E-01** per acre in water. Use lower rates when applying to shallow water (<1 foot deep). Use higher application rates to treat deeper water (>1 foot deep), to sites with dense vegetation, or when application conditions require treatments to be made earlier in development than recommended

## APPLICATION SITES

### PASTURES:

**B2E-01** may be applied, without removal of grazing livestock. **B2E-01** may be applied to 4th instar larvae of pasture mosquitoes. **B2E-01** treatment may be repeated as needed with each flooding.

### INTERMITTENTLY FLOODED NONCROP AREAS:

**B2E-01** may be applied to floodwater mosquito habits such as: freshwater swamps and marshes, salt marshes, woodland pools and meadows, dredging spoil sites, drainage areas, waste treatment and settling ponds, ditches and other natural and man made depressions.

### CROP AREAS:

Apply **B2E-01** to irrigated croplands to prevent adult mosquito emergence. Examples of such sites are: vineyards, rice fields (including wild rice), orchards, and berry fields and bogs. Irrigated pastures may be treated after each flooding without the removal of livestock.

### DENSE VEGETATION OR CANOPY AREAS:

Use **B2E-01** to make granules on sand or other carrier following preparation instructions detailed on the label. Apply **B2E-01** Granules using standard granular dispersal equipment.

## AERIAL & GROUND

Use the recommended amount of **B2E-01** listed below in sufficient water to give complete coverage. Do not apply when weather conditions will cause drift from the areas to be treated. Use **B2E-01** Granules to make treatments under windy conditions or to dense vegetation.

### To Make B2E-01 Granules:

Granules can be made using washed, dry sand or other carriers. Apply **B2E-01** to the granule quantity to be applied per acre. For example, to apply 1.0 fl. oz./acre dosage rate on 5 pounds of granules per acre: Add 98 pounds of washed dry sand into a small rotary cement mixer. Tilt mixer to an angle 20° above horizontal. Measure out 20 fl. oz. of **B2E-01**, and add to a sprayer equipped with a flat fan nozzle. Pressurize sprayer and turn on mixer. Spray **B2E-01** on the rolling face of the sand until it is evenly dampened. Mix for 2 minutes, then add a drying agent (Microcel E or Hisil 233) as needed, to achieve a dry, free flowing granule. Discharge and bag. Apply within 72 hours.

Refer to table below for the number of ounces used to make 100 pound batches of granules applied at different rates per acre.

Dosage Rate Oz./Acre	Granule Application Rate/Acre (Lbs.)	Ounces of B2E-01 applied to granules
0.5	2.5	20
0.5	5.0	10
0.5	10.0	5
1.0	2.5	40
1.0	5.0	20
1.0	10.0	10
1.5	2.5	60
1.5	5.0	30
1.5	10.0	15

# B2E-01 MASTER LABEL

## An Insect Growth Regulator

*(to control insect pests in tobacco processing and storage facilities)*

*(to prevent emergence of adult Sciarid flies in mushroom culture)*

*(to prevent the emergence of stored product insects)*

*(to prevent the emergence of adult filter flies & non-biting midges)*

*(to prevent the emergence of adult floodwater mosquitoes)*

### ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6) . . . . . 33.6%

OTHER INGREDIENTS\* . . . . . 66.4%

Total: . . . . . 100.0%

This product contains 2.748 lb/gallon (329.3 grams/liter) (S)-Methoprene active ingredient

EPA Reg No. 75318-

EPA Est. No.

B2E Biotech LLC

500 Mamaroneck Avenue

Harrison, NY 10528

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**See additional precautionary statements**

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### FIRST AID

##### If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
- Call a poison control center or doctor for treatment advice.

##### If on skin

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

##### If swallowed

- Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person.
- Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

### ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of rinsate or equipment washwaters.



## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### STORAGE

Store in a cool place.

### PESTICIDE DISPOSAL

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions. Always read the label before using this product.

In case of an emergency, call Chem-Tel at 1-xxx-xxx-xxxx.

For information visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

### *(Directions for Use for B2E-01 to control insect pests in tobacco processing and storage facilities)*

## FOR PROTECTION OF STORED TOBACCO FROM DAMAGE BY CIGARETTE BEETLE (*LASIODERMA SERRICORNE*) AND TOBACCO MOTH (*EPHESTIA ELUTELLA*)

### INTRODUCTION

B2E-01 is a water based emulsifiable formulation of the insect growth regulator, (S)-Methoprene. It is designed for use as a space spray in cold aerosol generators and in liquid concentrate form as an aqueous emulsified spray. Unlike traditional pesticides, (S)-Methoprene does not immediately kill immature insects; instead, it interferes with the normal insect development process and prevents adult pest emergence. B2E-01, prevents the adult emergence and reproduction of the Cigarette beetle (*Lasioderma serricorne*) and Tobacco moth (*Ephestia elutella*) when used according to label directions.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

#### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment that will achieve uniform dispersal for best treatment results.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for a minimum of 30 minutes (longer if possible) to allow the fine spray mist to settle. Do not remain in treated areas after treating. Ventilate treated areas before reentry. Repeat application as required.

#### APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Repeat application as required.

#### MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.



***(Directions for Use for B2E-01 prevent emergence of adult sciarid flies in mushroom culture)***

**AN INSECT GROWTH REGULATOR TO PREVENT THE EMERGENCE OF ADULT SCIARID FLIES IN MUSHROOM CULTURE**

**INTRODUCTION**

S-Methoprene, the active ingredient in **B2E-01** insect growth regulator (IGR), is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of S-Methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. **B2E-01** prevents the emergence of adult Sciarid flies from the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adult flies present at the time of application will not be affected. If high adult fly populations are present initially, use of a conventional adulticide will insure the best overall results. After treatment with **B2E-01**, larvae will continue to develop to the pupal stage where they will die. As **B2E-01** prevents adult fly emergence, adult fly populations will be reduced over time. As maximum control is achieved two weeks after treatment, control assessment should be made at this time for most accurate evaluation.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**Personal Protection Equipment (PPE)**

Some materials that are chemical-resistant to this product are listed below. For more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber (≥14 mils), barrier laminate, or viton (≥14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**Engineering Control Statements:**

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)]. The handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

**User Safety Recommendations:**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses on this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: if the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.



PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber, (≥14 mils), barrier laminated, or viton (≥14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.

## **METHOD, RATE, AND TIMING OF APPLICATION**

For best results, **B2E-01** should be incorporated in the mushroom growing medium.

Follow either METHOD A, METHOD B, METHOD C, METHOD D or METHOD E

### **APPLICATION INSTRUCTIONS:**

#### **A. INCORPORATE AT TIME OF CASING**

Mix **B2E-01** at the rate of 5½ fl. oz. per 1,000 sq ft. Make spray application evenly, and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface immediately after placement.

#### **B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING WHEN CASING LAYER IS PLACED ON COMPOST**

##### **In Compost:**

Mix **B2E-01** at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution. Spray on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

##### **In Casing:**

Mix **B2E-01** at the rate of 2¾ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application, On Compost:**

Apply **B2E-01** 12 to 13 days after spawning. Drench **B2E-01** evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

##### **Second Application, In Casing:**

Apply **B2E-01** at the rate of 2¾ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS**

##### **First Application, In Casing:**

Apply **B2E-01** at the rate of 5½ fl. oz. per 1,000 sq. ft. in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

##### **Second Application, On casing surface just prior to break:**

Apply **B2E-01** at the rate of 2¾ fl. oz. of per 1,000 sq. ft. in adequate water for even distribution as a surface drench prior to first break of mushrooms.

#### **E. DELAYED CASING SURFACE DRENCH**

### **APPLICATION INSTRUCTIONS:**

#### **A. Surface drench 7 days after casing**

Apply **B2E-01** 7 days after casing. Drench **B2E-01** evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### **B. Surface drench 7 days and 14 days after casing**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application on Casing:**

Apply **B2E-01** 7 days after casing. Drench **B2E-01** evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.



### Second Application on Casing:

Apply B2E-01 14 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.

## MIXING AND HANDLING INSTRUCTIONS

1. Shake container before using.
2. Add the measured amount of B2E-01 to a spray tank partially filled with water, mix, and complete filling with recommended quantity of water.
3. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## EFFECT ON MUSHROOMS

In most cases, treatment with B2E-01 has a beneficial effect on mushroom yield by reducing Sciarid fly larval damage. As mushroom production practices differ among growers, the user should conduct small plots treatments to verify that reduced crop yields will not occur under cultural conditions used.

### **(Directions for Use for B2E-01 to prevent the emergence of stored product insects)**

## AN INSECT GROWTH REGULATOR TO CONTROL STORED PRODUCT INSECTS

### INTRODUCTION

The active ingredient in B2E-01, (S)-Methoprene, protects stored grains from damaging insects by preventing insect development and adult emergence. Unlike traditional pesticides, B2E-01 is not an adulticide, but its residual activity interferes with reproduction and prevents treated larvae from developing into adults. B2E-01, when used according to the label directions, prevents regeneration of the following insects: Almond Moth (*Ephestia cautella*), Indian Meal Moth (*Plodia interpunctella*), Cigarette Beetle (*Lasioderma serricorne*), Lesser Grain Beetle (*Rhyzopertha dominica*), Sawtooth Grain Beetle (*Oryzaephilus surinamensis*), Merchant Grain Beetle (*Oryzaephilus mercator*), Red Flour Beetle (*Tribolium castaneum*), and Confused Flour Beetle (*Tribolium confusum*). Existing insect populations should be treated with an approved adulticide to kill adult pests before applying B2E-01 for residual protection. If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

**Stored Grain:** For maximum protection of stored food, feed, oil, and seed grains from stored grain insect damage, thoroughly clean and treat grain storage areas prior to storage of grain. B2E-01 may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 to 5 ppm for this application. Do not flood top-dress area.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED:** Dilute B2E-01 with water and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of B2E-01 on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply. Do not use rate less than 1 ppm. B2E-01 is to be applied in solution in accordance with the general directions to stored products at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of B2E-01. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

	5 ppm		2.5 ppm		1 ppm	
	fl oz	ml	fl oz	ml	fl oz	ml
Wheat	7.70	228	4.0	114	1.54	46
Corn	7.10	212	3.5	106	1.42	43
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43
Barley	6.10	182	3.0	91	1.22	37
Rice	5.70	170	3.0	85	1.10	34
Oats	4.10	121	2.0	61	0.80	25
Peanuts	3.85	115	2.0	60	0.80	24



## USE PRECAUTIONS:

- Apply B2E-01 grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of B2E-01 to a spray tank partially filled with water mix, and complete filling with specified quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Do not treat at extremely dusty sites. B2E-01 may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins, or other stored commodity areas. For application of B2E-01 as a fogging or space spray, use the following directions.

## APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment. Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

## APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

## MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 48 hours of mixing. Agitate before each use.

*(Directions for Use for B2E-01 to prevent the emergence of adult filter flies & non-biting midges)*

## PREVENTS THE EMERGENCE OF ADULT FILTER FLIES AND MIDGES - KEEPS INFESTATIONS UNDER CONTROL

## INTRODUCTION

B2E-01 is a unique water based product that controls filter flies (*Psychodidae*), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. B2E-01 contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. B2E-01 does not control adults but prevents the larval stage from developing into flying adults. B2E-01 keeps pest infestations under control by stopping the reproduction cycle, without shutting down your treatment facility. Regular use of B2E-01 prevents these pests from developing into annoying infestations.

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

## MIXING AND HANDLING INSTRUCTIONS:

Partially fill application tank with water; then add the specified amount of B2E-01, and complete filling with recommended quantity of water. Agitate before application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

## RECOMMENDED APPLICATIONS

### WASTE WATER TREATMENT FACILITY PESTS

Use B2E-01 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

### WHAT TO EXPECT IN CONTINUOUS FLOW WASTE WATER TREATMENT FACILITIES

To achieve effective results, B2E-01 must be applied to continuous flow systems on a daily basis for at least two weeks. A gradual reduction in the number of adult pests will be seen over a 7 day period with significant reduction seen after 14 days of treatment. Failure to apply B2E-01 daily may produce erratic results. Very heavy infestations often require slightly longer to achieve the desired control level. Since the mode of action



of B2E-01 is to prevent adult emergence, pupa and adults present at the time of initial application will complete their life cycle. Pest populations can be expected to rebound within 2-4 weeks following the last day of treatment. Insect monitoring traps, such as sticky paper can be used to monitor pest population rebound to determine when re-treatment should be initiated. Re-treatment intervals will vary depending on treatment plant design and size.

#### **SLUDGE OR SOLID WASTE APPLICATIONS**

For sludge solid waste applications, a high rate is recommended. Apply dilution until the drying beds have been filled, then stop the application. Applications should be made at the influent side where the sludge or solids enter into the drying beds. Application of B2E-01 to solids will prevent pest insect emergence thereby keeping infestations under control.

#### **METHODS OF APPLICATION**

Dilute B2E-01 with water prior to use. Apply B2E-01 by use of a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence product dilution. Treatments should be made over a 4 hour period during the lowest flow period of the day. It is important to calibrate delivery devices to dispense the required amount of B2E-01 over a 4 hour period to ensure effective control. In the case of sludge beds, B2E-01 should be applied until the beds have been filled.

#### **APPLICATION RATES**

To control waste water pests, apply 3 - 5 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply at the influent side over a 4 hour period during the lowest flow period of the day. For best results, make the application on a daily basis for two weeks without interruption.

#### **APPLICATION SITES**

Make applications of B2E-01 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem. Make B2E-01 applications as the sewage enters (influent areas) the waste water treatment area. Failure to add the material at the influent side may produce erratic results.

*(Directions for Use for B2E-01 to prevent the emergence of adult floodwater mosquitoes)*

### **PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES**

#### **INTRODUCTION**

B2E-01 provides effective levels of S-Methoprene insect growth regulator to control single broods of floodwater mosquitoes. B2E-01 prevents the emergence of adult floodwater mosquitoes (*Aedes*, *Ochloratus* and *Psorophora*) from treated water. Treated larvae continue to develop normally to the pupal stage where they die. The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **MIXING AND HANDLING INSTRUCTIONS**

1. B2E-01 is a water emulsifiable concentrate which requires agitation for uniform suspension. Separation may occur on standing, thus agitate prior to application.
2. Use clean equipment.
3. Partially fill spray tank with water; then add B2E-01, agitate and complete filling.
4. Spray solutions should be used within 48 hours; always agitate before and during spraying.

#### **RECOMMENDED APPLICATIONS**

B2E-01 should be applied to 4th instar floodwater mosquito larvae prior to pupation to prevent adult emergence. As 4<sup>th</sup> instar larvae stop feeding 12 to 18 hours before pupation, it is essential that treatments be made before cessation of feeding. Apply B2E-01 in the late afternoon or evening to extend control activity. Correct treatment timing is very important for best results. Treated larvae continue normal development to the pupal stage where they die. The active ingredient has no effect when applied to pupae or adult mosquitoes.



## APPLICATION RATES

Apply 0.5 ounce to 1.5 ounces (15 to 44 ml) of **B2E-01** per acre in water. Use lower rates when applying to shallow water (<1 foot deep). Use higher application rates to treat deeper water (>1 foot deep), to sites with dense vegetation, or when application conditions require treatments to be made earlier in development than recommended

## APPLICATION SITES

### PASTURES:

**B2E-01** may be applied, without removal of grazing livestock. **B2E-01** may be applied to 4th instar larvae of pasture mosquitoes. **B2E-01** treatment may be repeated as needed with each flooding.

### INTERMITTENTLY FLOODED NONCROP AREAS:

**B2E-01** may be applied to floodwater mosquito habits such as: freshwater swamps and marshes, salt marshes, woodland pools and meadows, dredging spoil sites, drainage areas, waste treatment and settling ponds, ditches and other natural and man made depressions.

### CROP AREAS:

Apply **B2E-01** to irrigated croplands to prevent adult mosquito emergence. Examples of such sites are: vineyards, rice fields (including wild rice), orchards, and berry fields and bogs. Irrigated pastures may be treated after each flooding without the removal of livestock.

### DENSE VEGETATION OR CANOPY AREAS:

Use **B2E-01** to make granules on sand or other carrier following preparation instructions detailed on the label. Apply **B2E-01** Granules using standard granular dispersal equipment.

## AERIAL & GROUND

Use the recommended amount of **B2E-01** listed below in sufficient water to give complete coverage. Do not apply when weather conditions will cause drift from the areas to be treated. Use **B2E-01** Granules to make treatments under windy conditions or to dense vegetation.

### To Make B2E-01 Granules:

Granules can be made using washed, dry sand or other carriers. Apply **B2E-01** to the granule quantity to be applied per acre. For example, to apply 1.0 fl. oz./acre dosage rate on 5 pounds of granules per acre: Add 98 pounds of washed dry sand into a small rotary cement mixer. Tilt mixer to an angle 20° above horizontal. Measure out 20 fl. oz. of **B2E-01**, and add to a sprayer equipped with a flat fan nozzle. Pressurize sprayer and turn on mixer. Spray **B2E-01** on the rolling face of the sand until it is evenly dampened. Mix for 2 minutes, then add a drying agent (Microcel E or Hisil 233) as needed, to achieve a dry, free flowing granule. Discharge and bag. Apply within 72 hours.

Refer to table below for the number of ounces used to make 100 pound batches of granules applied at different rates per acre.

Dosage Rate Oz./Acre	Granule Application Rate/Acre (Lbs.)	Ounces of B2E-01 applied to granules
0.5	2.5	20
0.5	5.0	10
0.5	10.0	5
1.0	2.5	40
1.0	5.0	20
1.0	10.0	10
1.5	2.5	60
1.5	5.0	30
1.5	10.0	15

# B2E-01 MASTER LABEL

## An Insect Growth Regulator

*(to control insect pests in tobacco processing and storage facilities)*

*(to prevent emergence of adult Sciarid flies in mushroom culture)*

*(to prevent the emergence of stored product insects)*

*(to prevent the emergence of adult filter flies & non-biting midges)*

*(to prevent the emergence of adult floodwater mosquitoes)*



### ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6) . . . . . 33.6%

OTHER INGREDIENTS\* . . . . . 66.4%

Total . . . . . 100.0%

This product contains 2.748 lb/gallon (329.3 grams/liter) (S)-Methoprene active ingredient

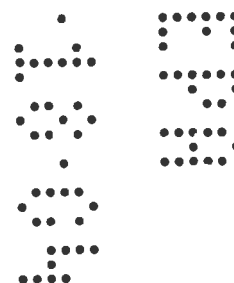
EPA Reg No. 75318-

EPA Est. No.

B2E Biotech LLC

500 Mamaroneck Avenue

Harrison, NY 10528



**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**See additional precautionary statements**

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

#### FIRST AID

##### If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
- Call a poison control center or doctor for treatment advice.

##### If on skin

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

##### If swallowed

- Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person.
- Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

### ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of rinsate or equipment washwaters.



## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

### STORAGE

Store in a cool place.

### PESTICIDE DISPOSAL

Wastes resulting from this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Triple rinse or equivalent, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions. Always read the label before using this product.

In case of an emergency, call Chem-Tel at 1-xxx-xxx-xxxx.

For information visit our web site: [www.\\_\\_\\_\\_\\_.com](http://www._____.com)

### *(Directions for Use for B2E-01 to control insect pests in tobacco processing and storage facilities)*

## FOR PROTECTION OF STORED TOBACCO FROM DAMAGE BY CIGARETTE BEETLE (*LASIODERMA SERRICORNE*) AND TOBACCO MOTH (*EPHESTIA ELUTELLA*)

### INTRODUCTION

B2E-01 is a water based emulsifiable formulation of the insect growth regulator, (S)-Methoprene. It is designed for use as a space spray in cold aerosol generators and in liquid concentrate form as an aqueous emulsified spray. Unlike traditional pesticides, (S)-Methoprene does not immediately kill immature insects; instead, it interferes with the normal insect development process and prevents adult pest emergence. B2E-01, prevents the adult emergence and reproduction of the Cigarette beetle (*Lasioderma serricorne*) and Tobacco moth (*Ephestia elutella*) when used according to label directions.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

#### APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment that will achieve uniform dispersal for best treatment results.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for a minimum of 30 minutes (longer if possible) to allow the fine spray mist to settle. Do not remain in treated areas after treating. Ventilate treated areas before reentry. Repeat application as required.

#### APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Repeat application as required.

#### MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.



***(Directions for Use for B2E-01 prevent emergence of adult sciarid flies in mushroom culture)***

**AN INSECT GROWTH REGULATOR TO PREVENT THE EMERGENCE OF ADULT SCIARID FLIES IN MUSHROOM CULTURE**

**INTRODUCTION**

S-Methoprene, the active ingredient in **B2E-01** insect growth regulator (IGR), is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of S-Methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. **B2E-01** prevents the emergence of adult Sciarid flies from the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adult flies present at the time of application will not be affected. If high adult fly populations are present initially, use of a conventional adulticide will insure the best overall results. After treatment with **B2E-01**, larvae will continue to develop to the pupal stage where they will die. As **B2E-01** prevents adult fly emergence, adult fly populations will be reduced over time. As maximum control is achieved two weeks after treatment, control assessment should be made at this time for most accurate evaluation.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**Personal Protection Equipment (PPE)**

Some materials that are chemical-resistant to this product are listed below. For more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber (≥14 mils), barrier laminate, or viton (≥14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**Engineering Control Statements:**

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)]. The handler PPE requirements may be reduced or modified as specified in the WPS.

**IMPORTANT:** When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

**User Safety Recommendations:**

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses on this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: if the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.



PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥14 mils), nitrile rubber, (≥14 mils), barrier laminated, or viton (≥14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.

## **METHOD, RATE, AND TIMING OF APPLICATION**

For best results, **B2E-01** should be incorporated in the mushroom growing medium.

Follow either METHOD A, METHOD B, METHOD C, METHOD D or METHOD E

### **APPLICATION INSTRUCTIONS:**

#### **A. INCORPORATE AT TIME OF CASING**

Mix **B2E-01** at the rate of 5½ fl. oz. per 1,000 sq ft. Make spray application evenly, and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface immediately after placement.

#### **B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING WHEN CASING LAYER IS PLACED ON COMPOST**

##### **In Compost:**

Mix **B2E-01** at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution. Spray on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

##### **In Casing:**

Mix **B2E-01** at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application, On Compost:**

Apply **B2E-01** 12 to 13 days after spawning. Drench **B2E-01** evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

##### **Second Application, In Casing:**

Apply **B2E-01** at the rate of 2¼ fl. oz. per 1,000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

#### **D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS**

##### **First Application, In Casing:**

Apply **B2E-01** at the rate of 5½ fl. oz. per 1,000 sq. ft. in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

##### **Second Application, On casing surface just prior to break:**

Apply **B2E-01** at the rate of 2¼ fl. oz. of per 1,000 sq. ft. in adequate water for even distribution as a surface drench prior to first break of mushrooms.

#### **E. DELAYED CASING SURFACE DRENCH**

### **APPLICATION INSTRUCTIONS:**

#### **A. Surface drench 7 days after casing**

Apply **B2E-01** 7 days after casing. Drench **B2E-01** evenly on the surface at the rate of 5½ fl. oz. per 1,000 sq ft in adequate water for even distribution.

#### **B. Surface drench 7 days and 14 days after casing**

For those crops that have a spawn run longer than 15 days, a split application can be used.

##### **First Application on Casing:**

Apply **B2E-01** 7 days after casing. Drench **B2E-01** evenly on the surface at the rate of 2¼ fl. oz. per 1,000 sq ft in adequate water for even distribution.

### Second Application on Casing:

Apply B2E-01 14 days after casing. Drench B2E-01 evenly on the surface at the rate of 2¾ fl. oz. per 1,000 sq ft in adequate water for even distribution.

## MIXING AND HANDLING INSTRUCTIONS

1. Shake container before using.
2. Add the measured amount of B2E-01 to a spray tank partially filled with water, mix, and complete filling with recommended quantity of water.
3. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

## EFFECT ON MUSHROOMS

In most cases, treatment with B2E-01 has a beneficial effect on mushroom yield by reducing Sciarid fly larval damage. As mushroom production practices differ among growers, the user should conduct small plots treatments to verify that reduced crop yields will not occur under cultural conditions used.

### *(Directions for Use for B2E-01 to prevent the emergence of stored product insects)*

## AN INSECT GROWTH REGULATOR TO CONTROL STORED PRODUCT INSECTS

### INTRODUCTION

The active ingredient in B2E-01, (S)-Methoprene, protects stored grains from damaging insects by preventing insect development and adult emergence. Unlike traditional pesticides, B2E-01 is not an adulticide, but its residual activity interferes with reproduction and prevents treated larvae from developing into adults. B2E-01, when used according to the label directions, prevents regeneration of the following insects: Almond Moth (*Ephestia cautella*), Indian Meal Moth (*Plodia interpunctella*), Cigarette Beetle (*Lasioderma serricorne*), Lesser Grain Beetle (*Rhyzopertha dominica*), Sawtooth Grain Beetle (*Oryzaephilus surinamensis*), Merchant Grain Beetle (*Oryzaephilus mercator*), Red Flour Beetle (*Tribolium castaneum*), and Confused Flour Beetle (*Tribolium confusum*). Existing insect populations should be treated with an approved adulticide to kill adult pests before applying B2E-01 for residual protection. If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

**Stored Grain:** For maximum protection of stored food, feed, oil, and seed grains from stored grain insect damage, thoroughly clean and treat grain storage areas prior to storage of grain. B2E-01 may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 to 5 ppm for this application. Do not flood top-dress area.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED:** Dilute B2E-01 with water and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of B2E-01 on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply. Do not use rate less than 1 ppm. B2E-01 is to be applied in solution in accordance with the general directions to stored products at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of B2E-01. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

	5 ppm		2.5 ppm		1 ppm	
	fl oz	ml	fl oz	ml	fl oz	ml
Wheat	7.70	228	4.0	114	1.54	46
Corn	7.10	212	3.5	106	1.42	43
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43
Barley	6.10	182	3.0	91	1.22	37
Rice	5.70	170	3.0	85	1.10	34
Oats	4.10	121	2.0	61	0.80	25
Peanuts	3.85	115	2.0	60	0.80	24



## USE PRECAUTIONS:

- Apply B2E-01 grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of B2E-01 to a spray tank partially filled with water mix, and complete filling with specified quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Do not treat at extremely dusty sites. B2E-01 may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins, or other stored commodity areas. For application of B2E-01 as a fogging or space spray, use the following directions.

## APPLICATION WITH COLD AEROSOL GENERATORS

Apply B2E-01 as a mist or aerosol. Dilute with water following the instructions of the spray equipment manufacturer. Apply B2E-01 at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment. Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

## APPLICATION AS AN AQUEOUS SPRAY

Prepare a diluted spray solution by adding 1 ml of B2E-01 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

## MIXING INSTRUCTIONS

Partially fill the mixing container with water, add B2E-01, mix, and complete filling with quantity of water specified above. Use diluted spray solution within 48 hours of mixing. Agitate before each use.

*(Directions for Use for B2E-01 to prevent the emergence of adult filter flies & non-biting midges)*

## PREVENTS THE EMERGENCE OF ADULT FILTER FLIES AND MIDGES - KEEPS INFESTATIONS UNDER CONTROL

### INTRODUCTION

B2E-01 is a unique water based product that controls filter flies (*Psychodidae*), midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. B2E-01 contains an insect growth regulator (IGR) that effectively controls the last stage of these insect pests. B2E-01 does not control adults but prevents the larval stage from developing into flying adults. B2E-01 keeps pest infestations under control by stopping the reproduction cycle, without shutting down your treatment facility. Regular use of B2E-01 prevents these pests from developing into annoying infestations.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### MIXING AND HANDLING INSTRUCTIONS:

Partially fill application tank with water; then add the specified amount of B2E-01, and complete filling with recommended quantity of water. Agitate before application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

### RECOMMENDED APPLICATIONS

#### WASTE WATER TREATMENT FACILITY PESTS

Use B2E-01 in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

#### WHAT TO EXPECT IN CONTINUOUS FLOW WASTE WATER TREATMENT FACILITIES

To achieve effective results, B2E-01 must be applied to continuous flow systems on a daily basis for at least two weeks. A gradual reduction in the number of adult pests will be seen over a 7 day period with significant reduction seen after 14 days of treatment. Failure to apply B2E-01 daily may produce erratic results. Very heavy infestations often require slightly longer to achieve the desired control level. Since the mode of action



of B2E-01 is to prevent adult emergence, pupa and adults present at the time of initial application will complete their life cycle. Pest populations can be expected to rebound within 2-4 weeks following the last day of treatment. Insect monitoring traps, such as sticky paper can be used to monitor pest population rebound to determine when re-treatment should be initiated. Re-treatment intervals will vary depending on treatment plant design and size.

#### **SLUDGE OR SOLID WASTE APPLICATIONS**

For sludge solid waste applications, a high rate is recommended. Apply dilution until the drying beds have been filled, then stop the application. Applications should be made at the influent side where the sludge or solids enter into the drying beds. Application of B2E-01 to solids will prevent pest insect emergence thereby keeping infestations under control.

#### **METHODS OF APPLICATION**

Dilute B2E-01 with water prior to use. Apply B2E-01 by use of a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence product dilution. Treatments should be made over a 4 hour period during the lowest flow period of the day. It is important to calibrate delivery devices to dispense the required amount of B2E-01 over a 4 hour period to ensure effective control. In the case of sludge beds, B2E-01 should be applied until the beds have been filled.

#### **APPLICATION RATES**

To control waste water pests, apply 3 - 5 ounces of B2E-01 per 1 million gallons of sewage (waste water) in sufficient water to uniformly apply at the influent side over a 4 hour period during the lowest flow period of the day. For best results, make the application on a daily basis for two weeks without interruption.

#### **APPLICATION SITES**

Make applications of B2E-01 to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem. Make B2E-01 applications as the sewage enters (influent areas) the waste water treatment area. Failure to add the material at the influent side may produce erratic results.

*(Directions for Use for B2E-01 to prevent the emergence of adult floodwater mosquitoes)*

### **PREVENTS EMERGENCE OF ADULT FLOODWATER MOSQUITOES**

#### **INTRODUCTION**

B2E-01 provides effective levels of S-Methoprene insect growth regulator to control single broods of floodwater mosquitoes. B2E-01 prevents the emergence of adult floodwater mosquitoes (*Aedes*, *Ochloratus* and *Psorophora*) from treated water. Treated larvae continue to develop normally to the pupal stage where they die. The active ingredient S-Methoprene has no effect on mosquitoes that have reached the pupal or adult stage prior to treatment.

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **MIXING AND HANDLING INSTRUCTIONS**

1. B2E-01 is a water emulsifiable concentrate which requires agitation for uniform suspension. Separation may occur on standing, thus agitate prior to application.
2. Use clean equipment.
3. Partially fill spray tank with water; then add B2E-01, agitate and complete filling.
4. Spray solutions should be used within 48 hours; always agitate before and during spraying.

#### **RECOMMENDED APPLICATIONS**

B2E-01 should be applied to 4th instar floodwater mosquito larvae prior to pupation to prevent adult emergence. As 4<sup>th</sup> instar larvae stop feeding 12 to 18 hours before pupation, it is essential that treatments be made before cessation of feeding. Apply B2E-01 in the late afternoon or evening to extend control activity. Correct treatment timing is very important for best results. Treated larvae continue normal development to the pupal stage where they die. The active ingredient has no effect when applied to pupae or adult mosquitoes.



## APPLICATION RATES

Apply 0.5 ounce to 1.5 ounces (15 to 44 ml) of **B2E-01** per acre in water. Use lower rates when applying to shallow water (<1 foot deep). Use higher application rates to treat deeper water (>1 foot deep), to sites with dense vegetation, or when application conditions require treatments to be made earlier in development than recommended

## APPLICATION SITES

### PASTURES:

**B2E-01** may be applied, without removal of grazing livestock. **B2E-01** may be applied to 4th instar larvae of pasture mosquitoes. **B2E-01** treatment may be repeated as needed with each flooding.

### INTERMITTENTLY FLOODED NONCROP AREAS:

**B2E-01** may be applied to floodwater mosquito habits such as: freshwater swamps and marshes, salt marshes, woodland pools and meadows, dredging spoil sites, drainage areas, waste treatment and settling ponds, ditches and other natural and man made depressions.

### CROP AREAS:

Apply **B2E-01** to irrigated croplands to prevent adult mosquito emergence. Examples of such sites are: vineyards, rice fields (including wild rice), orchards, and berry fields and bogs. Irrigated pastures may be treated after each flooding without the removal of livestock.

### DENSE VEGETATION OR CANOPY AREAS:

Use **B2E-01** to make granules on sand or other carrier following preparation instructions detailed on the label. Apply **B2E-01** Granules using standard granular dispersal equipment.

## AERIAL & GROUND

Use the recommended amount of **B2E-01** listed below in sufficient water to give complete coverage. Do not apply when weather conditions will cause drift from the areas to be treated. Use **B2E-01** Granules to make treatments under windy conditions or to dense vegetation.

### To Make B2E-01 Granules:

Granules can be made using washed, dry sand or other carriers. Apply **B2E-01** to the granule quantity to be applied per acre. For example, to apply 1.0 fl. oz./acre dosage rate on 5 pounds of granules per acre: Add 98 pounds of washed dry sand into a small rotary cement mixer. Tilt mixer to an angle 20° above horizontal. Measure out 20 fl. oz. of **B2E-01**, and add to a sprayer equipped with a flat fan nozzle. Pressurize sprayer and turn on mixer. Spray **B2E-01** on the rolling face of the sand until it is evenly dampened. Mix for 2 minutes, then add a drying agent (Microcel E or Hisil 233) as needed, to achieve a dry, free flowing granule. Discharge and bag. Apply within 72 hours.

Refer to table below for the number of ounces used to make 100 pound batches of granules applied at different rates per acre.

Dosage Rate Oz./Acre	Granule Application Rate/Acre (Lbs.)	Ounces of B2E-01 applied to granules
0.5	2.5	20
0.5	5.0	10
0.5	10.0	5
1.0	2.5	40
1.0	5.0	20
1.0	10.0	10
1.5	2.5	60
1.5	5.0	30
1.5	10.0	15

